HEIDELBERG ENGINEERING

Heidelberg Retina Angiograph 2

HRA 2

Operation Manual

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The manufacturer hereby declares that this product conforms to the requirements of Directive 93/42/EEC of the Council of the European Community dated 14 June 1993 regarding medical products (MDD 93/42/EEC).

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1 Introduction

1.1 Intended use

The Heidelberg Retina Angiograph 2 is a diagnostic device for the human eye.

Intended use is for the examination of the retina by laser scanning either with or without contrast agent, resp. fluorescence agent). The purpose of the angiography testing is to assist in the diagnosis of eye diseases. The diagnostic result shall provide help to the physician for adequate therapy.

1.2 The Heidelberg Retina Angiograph 2

The Heidelberg Retina Angiograph 2 is a confocal laser scanning system for digital fluorescein and indocyanine green angiography. Fluorescein and indocyanine green angiography can be performed either separately or simultaneously.

For acquisition of the digital confocal images, a laser beam with a wavelength suitable to excite the fluorescent dye is focused on the retina. The laser beam is deflected periodically by means of oscillating mirrors to sequentially scan a two-dimensional section of the retina. The intensity of the emitted fluorescent light at each point is measured with a light sensitive detector. In a confocal optical system, light emitted outside of the adjusted focal plane is suppressed. This suppression increases with the distance from the focal plane, and results in a high contrast image. Furthermore (especially during indocyanine green angiography), the confocal optical system allows the user to acquire three-dimensional images layer by layer, which is comparable to laser scanning tomography.

The laser sources contained in the Heidelberg Retina Angiograph 2 emit laser light of three different wavelengths: for fluorescein angiography, the blue line of a solid state laser (488 nm) is used to excite the fluorescein. A barrier filter at 500 nm edge wavelength separates excitation and fluorescent light. The same wavelength (but without barrier filter) is used to create red free reflectance images. For indocyanine green angiography, a diode laser at 795 nm wavelength is used to excite the dye, while a barrier filter at 810 nm edge wavelength separates excitation and fluorescent light. A second diode laser at 830 nm wavelength serves to produce infrared reflectance images.

Several image acquisition modes are provided, i.e. pure fluorescein angiography, pure indocyanine green angiography, and simultaneous fluorescein / indocyanine green angiography. In the simultaneous mode, each image line is scanned twice. During the first scan, fluorescein is excited and its fluorescence is measured; during the subsequent second scan, indocyanine green is excited and its fluorescence is measured. In every acquisition mode, individual images, time resolved image sequences, or a focal series of images (layered, three-dimensional images) can be acquired. The images are immediately digitized with a resolution between 384 x 384 and 1536 x 1536 pixels. The digitized images are stored in the computer's main memory and then saved on the computer's hard disk. The size of the field of view can be set to 15 x 15 degrees, 20 x 20 degrees, or 30 x 30 degrees.

2 Contraindications, Warnings, Precautions and Adverse Events

2.1 Contraindications

- Be aware of possible allergic reactions when contrast or dye fluid is injected.
- Asked the patient for known allergies and compare it with the contraindications of the contrast or dye fluid.

2.2 Warnings

- Carefully read the instructions for use before operating the device. Misuse of the device may lead to hazards for patient or user or lead to wrong diagnostic results.
- Do not open the device component housings. Doing so can lead to the possibility of electrical shock and laser radiation. See also subsection “3.4 Instrument Safety” and “3.4.2 Laser Safety”
- Do not use the device outside of the “Intended use” scope. Doing so may lead to malfunctions or damage of the device
- Do not use PCs, components or accessories that have not been approved by Heidelberg Engineering. Do not install other software programs as they may interfere with the functionality of the Heidelberg Engineering software or equipment. This could include damage to the system as well as incorrect measurement results.
- Do not operate the system without connecting the PC and components to an IEC 60601-1 proven isolation transformer. Doing so could lead to electrical shock to the user and patient in the case of a failure of the PC or to a PC accessory.
- Do not use a network connection without network isolation in accordance to IEC 60601-1. In case of a failure in the network, there could be a hazard of electrical shock to the user and patient.
- Make sure that the environmental requirements are met when the system is operated. Exceeding environmental conditions might damage the system or lead to wrong measuring results. (See subsection 7 “Technical Data”).
- Make sure the scanners are working (high pitched sound) before installing a patient in front of the device. No laser beam should be visible, when the scanners are off. A hazard for an injury of the retina would exist if the laser beam hits the retina without being scanned.
- Make sure the patient is correctly placed in front of the camera before starting the examination. Wrong positioning may lead to poor images and wrong diagnostic results.
- Artifacts on the images might falsify the measured results. Do not use the measured results for further treatment if there are artifacts in the images.
- Do make a diagnostic decision on one single examination. Always use alternative information; history data etc. to assist in a final diagnostic determination.

- Prepare safeguards to ensure that only authorized personnel can access the patient data. Data loss impedes follow up analyses and may result in wrong diagnostic decision.
- Be sure to perform periodic data backup procedures. Check the success of the backup to avoid data losses caused by backup errors.
- Do not operate the system directly after obvious climate changes. Let the device acclimate itself for a minimum of 2 hours to avoid device damage or wrong measurement results.

2.3 Precautions

- The operator shall be sure that the device settings and adjustments are correct before examination and diagnostic decision. Wrong settings and adjustments may lead to poor image quality or wrong examination information.
- The physician shall be sure to have the correct patient data before a diagnostic decision. Mismatched patient data may lead to wrong diagnostic decisions.
- Read chapter “5.1 Preparation” carefully before starting the examination. Incorrect preparation of the patient may lead to poor image quality and incorrect diagnoses.
- Do not start an examination without informing the patient about the examination procedure. Wrong patient behavior during the examination may lead to poor image quality and incorrect diagnoses.
- Clean and disinfect chin rest and head rest after each examination. Contaminated parts may lead to infections or disease contraction.
- Read chapter “7.8 Service, Maintenance and Cleaning” carefully. Missing maintenance or incorrect adjustment of the device may lead to poor image quality and incorrect diagnoses.
- Do not perform more than 1 examination per day on the same patient. Multiple injections of the contrast or dye fluid may lead to allergic reactions or shock.
- Before starting the system check the regional power supply specifications to verify that they fit the required tolerances ($100V < U < 240V$; $50Hz < f < 60Hz$). Wrong power supply conditions might lead to malfunctions of the system.
- Be aware that the influence of other physical effects (vibrations, strong electromagnetic fields as caused by big machines etc. running close-by), might disturb the proper operating of the device.
- A computer failure during picture acquisition or analysis could lead to incorrect results.

3 Installation and Safety Information

3.1 Components of the Instrument

The HRA2 system applies to the applicable standards of IEC 60601-1, IEC 60601-1-2, UL2601, and IEC 60825.

The basic components of the Heidelberg Retina Angiograph 2 are the:

- Laser scanning camera
- Camera mount with headrest
- Touch panel
- Power supply with Laser module
- Computer
- Isolation Transformer
- Operation software.

The laser scanning camera is the core of the Heidelberg Retina Angiograph 2. It contains the three-dimensional scanning system, the detector and the main part of the electronics. The solid state 488nm laser source is located in the laser module and is coupled to the camera via an optical fiber. The diode lasers for infrared and indocyanine green angiography are located in the laser scanning camera. The scanning laser beam emerges from the objective on the front of the camera. The intensity of the emitted fluorescent light is also measured through this objective.

The laser scanning camera is mounted on a special camera mount which also contains the headrest for the patient. The camera mount is designed so that the measuring position on the ocular fundus can be selected by rotating the camera around two orthogonal axes.

The control panel is used to control image acquisition. Here, the basic image acquisition parameters such as angiography type, laser intensity, detector sensitivity, size of the scanning field and position of the focal plane are specified. The image acquisition itself is initiated from the control panel.

The laser module contains one solid state laser. The laser light is transmitted into the laser scanning camera via one fiber optic. The laser scanning camera contains two diode lasers.

The power supply supplies voltage to the laser scanning camera. The on/off switch is located on the front panel. With the switch in position O, the power supply is turned off.

The Heidelberg Retina Angiograph 2 is operated by a PC-compatible personal computer in combibnation with a IEC 60601-1 proven isolation transformer. The computer receives the image data generated by the laser scanning camera and performs the entire image analysis. For this purpose, special hardware is installed in the computer in addition to the Heidelberg Retina Angiograph 2 operation software.

The operation software includes functions to communicate with the user, to control image acquisition, to store images and data, to process and analyze the acquired images, and to document the examination results.

3.2 Scope of delivery

The scope of delivery for this instrument consists of the following parts:

- Laser scanning camera
- Touch panel
- Foot switch
- Camera mount with integrated headrest
- Power supply with Laser module
- Frame grabber module for installation in the personal computer
- Cable - touch panel to power supply
- Cable - frame grabber module to power supply
- Cable - frame grabber module to camera
- CD containing operation software
- Software protector
- Operation manual
- Personal computer with hard disk, floppy drive, magneto-optic drive, VGA board, color monitor, keyboard, mouse, Microsoft Windows 2000/XP operating system.
- Isolation transformer with connector cables.

3.3 Installing the Instrument

(1) Assemble the headrest according to the separate set of instructions. The headrest should be mounted firmly on the table top.

(2) Place the camera mount onto the sliding platform of the headrest.

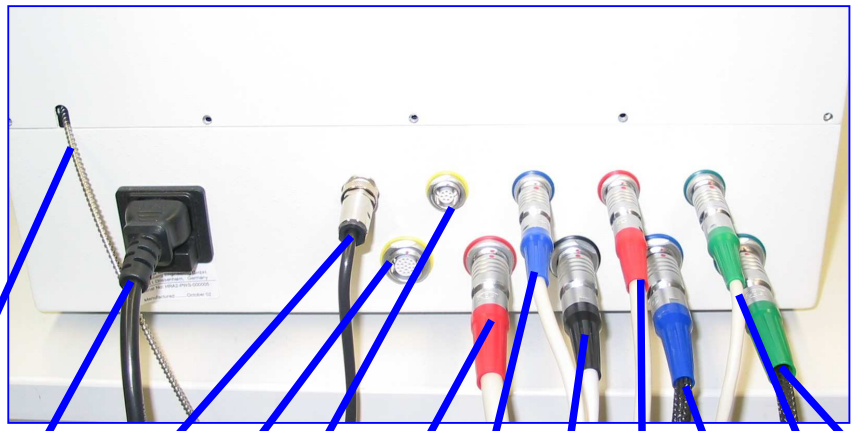
(3) Install the frame grabber board into the computer.

(4) Assemble the computer and connect the monitor, keyboard and mouse.

(5) Connect all the power cables (PC, Monitor, Printer and Power Supply) to the isolation transformer.
Caution:
Do not operate the system without an isolation transformer. Doing so will void the warranty !
It is not allowed to operate PC components in the patients environment without separation via an isolation transformer.

(5) Connect all cables between camera, laser box and PC in accordance to the connection diagram shown below.
Make sure that all cables are in good condition correctly inserted.

The picture below shows the cable connections to the back of the Laser Box:



Metal shielded fiber connected to the camera	AC- Power Supply (110 / 230V)	Foot Switch	Debug and Service interface (not connected in normal operation)	Expansion Interface (not connected in normal operation)	Data Cable connected to the camera	Left- Right recognition connected to camera mount	Camera power supply connected to the camera	Touch panel interface	Frame Grabber Signals from the camera	RS232 interface to PC-serial port (COM1, COM2)	Frame grabber Signals to PC- Frame Grabber Board

3.4 Instrument Safety

Important! Before you start working with the instrument, make sure that you know the correct procedures for turning the instrument on and off (“Chapter 4 General Operating Information”). Do not leave the patient alone with the instrument during the examination.

3.4.1 General Information

The instrument must not be used if there is a mechanical, electrical, or optical defect. Any modifications or additions which are made to the instrument must comply with the relevant legal guidelines. Any repair, especially of the instrument's electric and electronic systems, and any service work on the instrument components, must only be carried out by appropriately qualified and authorized staff.

Caution! Unusual noises and/or vibrations may be symptoms of a fault in the instrument. Please turn the instrument off and contact your local service office. Do not attempt to repair any faults with the instrument yourself.

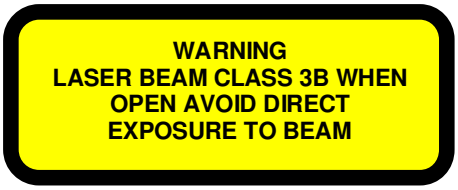
3.4.2 Laser Safety

This instrument contains a solid state laser and two diode lasers. The instrument emits visible and invisible laser light through the objective lens on the front of the laser scanning camera. The Heidelberg Retina Angiograph 2 is a Class 1 laser system. It does not pose any safety hazard whatsoever. The laser class label is located on the rear panel of the camera housing and the rear panel of the laser module:

However, hazardous laser radiation may be accessible when the camera housing or the housing of the laser module is open.

Caution! Never open the housing of the laser scanning camera or the laser module. When the camera housing or the laser module housing are open, visible and/or invisible laser radiation of Class IIIB is accessible and can lead to injuries. The camera housing and laser module housing must only be opened by qualified service staff.

Laser warning labels to this effect are positioned on the cover of the camera housing (underneath the electronics card which is located there) and on the rear side of the laser module:



To guarantee the safety of the user and the patient at all times, a limit has been imposed on the maximum period of time for which the laser beam can be switched on. If this limit is exceeded, the screen shows the message: 'Laser Safety; laser timed out'. Image acquisition is automatically interrupted and can only be continued after a specified waiting period (about 3 hours). However, this will not usually occur during normal use of the instrument.

3.5 Care

The Heidelberg Retina Angiograph 2 is a precision optical instrument. Please protect the instrument from dust and moisture, and avoid subjecting it to shocks or strong forces.

The lens surface on the front of the camera should be carefully cleaned at regular intervals (possibly every day). For this purpose, it is best to use acetone and a soft cotton ball.

The non-optical surfaces of the instrument can be cleaned and/or disinfected as usual whenever necessary. Before doing this, please turn the instrument off and pull out the power plug.

4 General Operating Information

4.1 Turning the Instrument On and Off

4.1.1 Turning On

To turn the Heidelberg Retina Angiograph 2 on, proceed as follows:

(1) Turn the computer on. After the boot sequence has been completed, the computer will start the Windows operating system.

(2) Turn on the power supply. The power switch is located on the front panel of the power supply. The 'off' position is marked O.

(3) Use the Heidelberg Eye Explorer shortcut on the desktop to start the application.

This will start the Heidelberg Eye Explorer software.

Note: It is not recommended to turn the instrument on and off frequently. Even if you are not using the instrument constantly during the course of a day, it is best to turn it on in the morning and not to turn it off again until the evening.

4.1.2 Turning Off

To turn the Heidelberg Retina Angiograph 2 off, proceed as follows:

(1) If the acquisition dialog is open and the live image is visible on the screen, stop the image acquisition with the 'freeze' button on the touch panel and leave the acquisition dialog.

(2) Turn off the power supply. The power switch is located on the front panel of the power supply. The 'off' position is marked O.

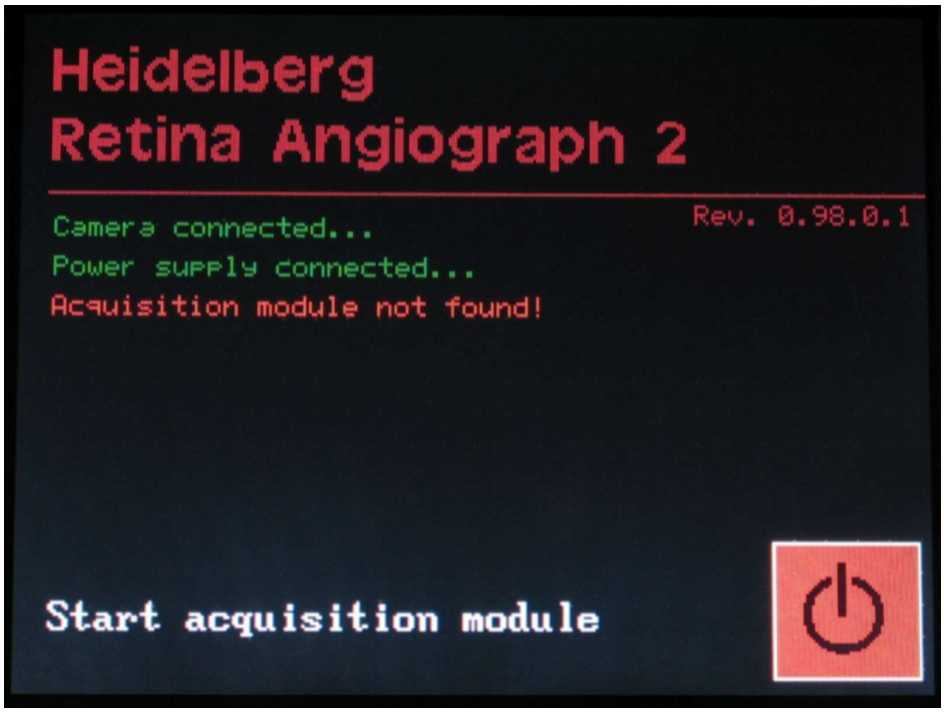
Important! Never turn off the power supply while the laser scanning camera is acquiring images. This can result in damage to the camera.
Never turn the computer off without quitting the Heidelberg Retina Angiograph 2 operation software first. This can result in the loss of data stored on the computer's hard disk. Before you turn off your computer, select "Shut Down" from the Windows "Start" menu.

4.2 Controls

4.2.1 Touch Panel

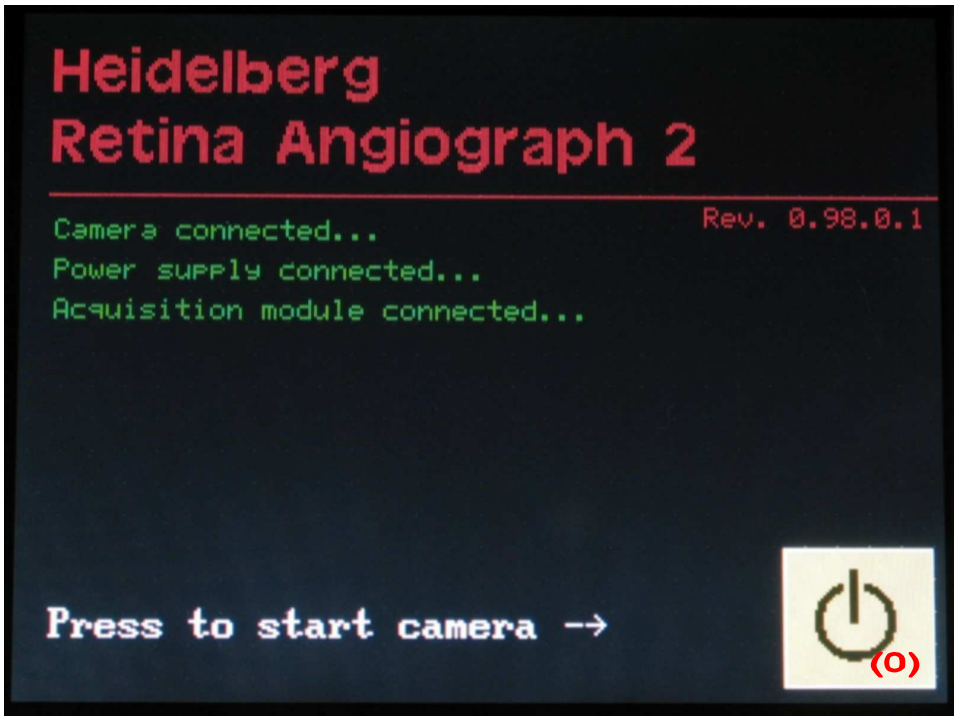
4.2.1.1 "Freeze" Screen

Immediately after switching on the device.



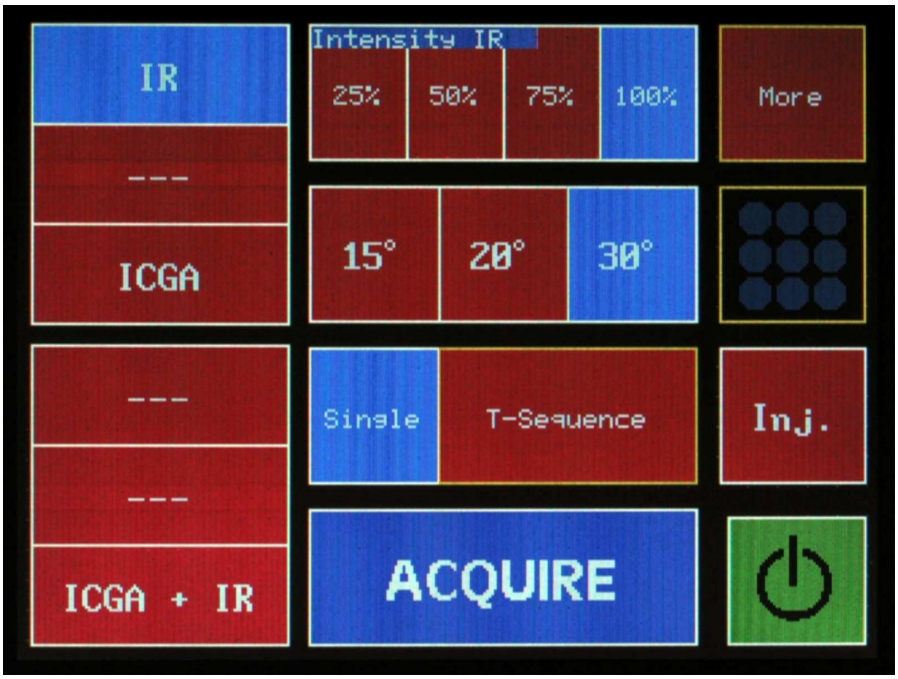
4.2.1.2 "Freeze" Screen:

HRA2 Acquisition Module started in Eye Explorer. Press button (0) to go to live mode (and therefore to main screen).



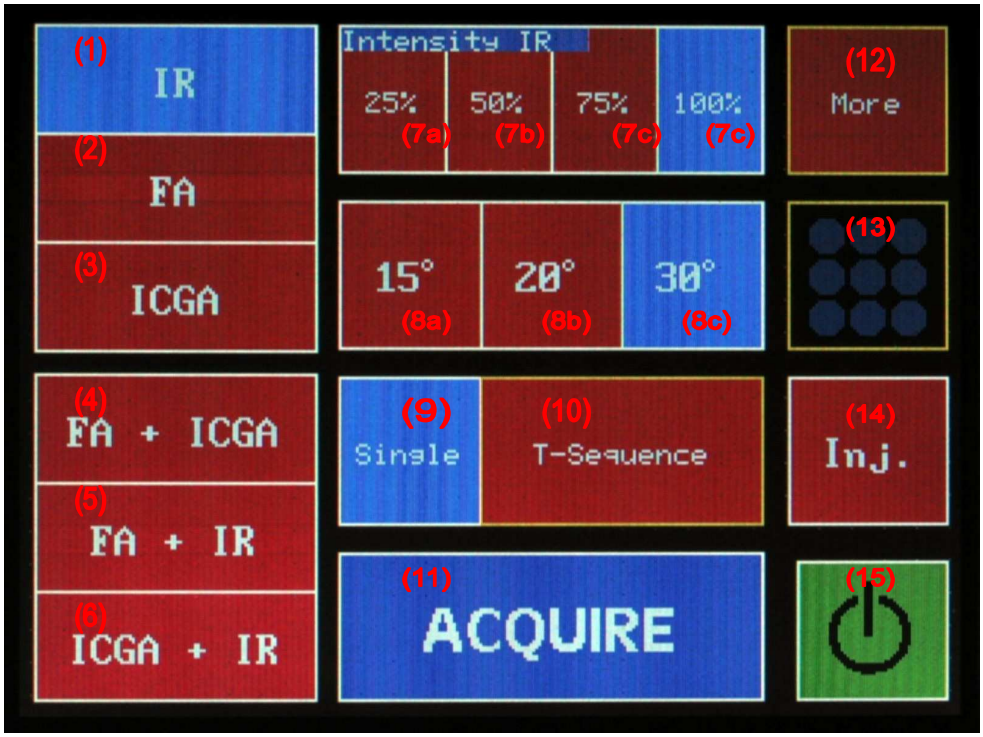
4.2.1.3 Main Screen

FA/Red Free modes are not available during warm-up (approx. ½ minute).



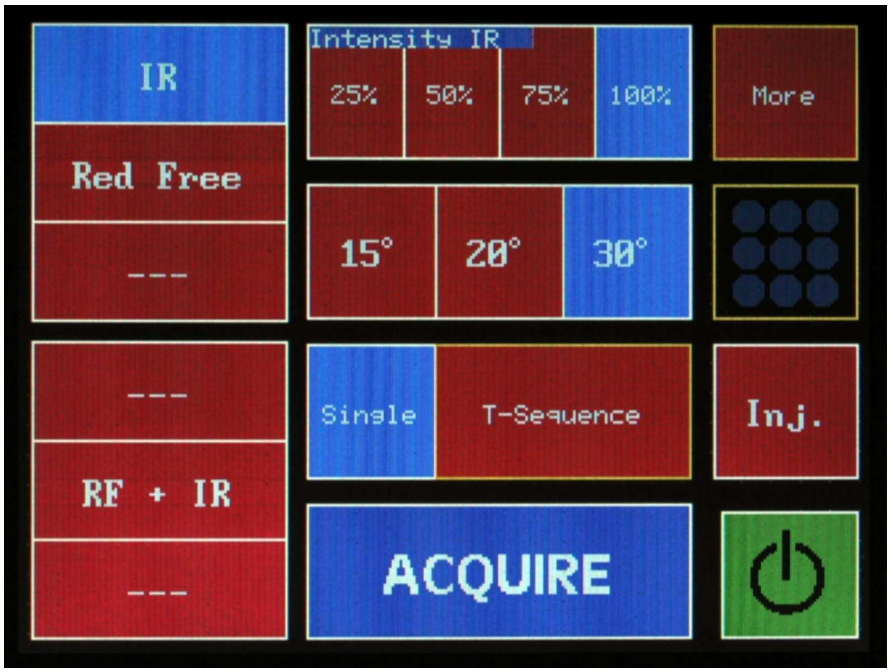
4.2.1.4 Main Screen

FA laser warmed up. Filter in angiography mode.



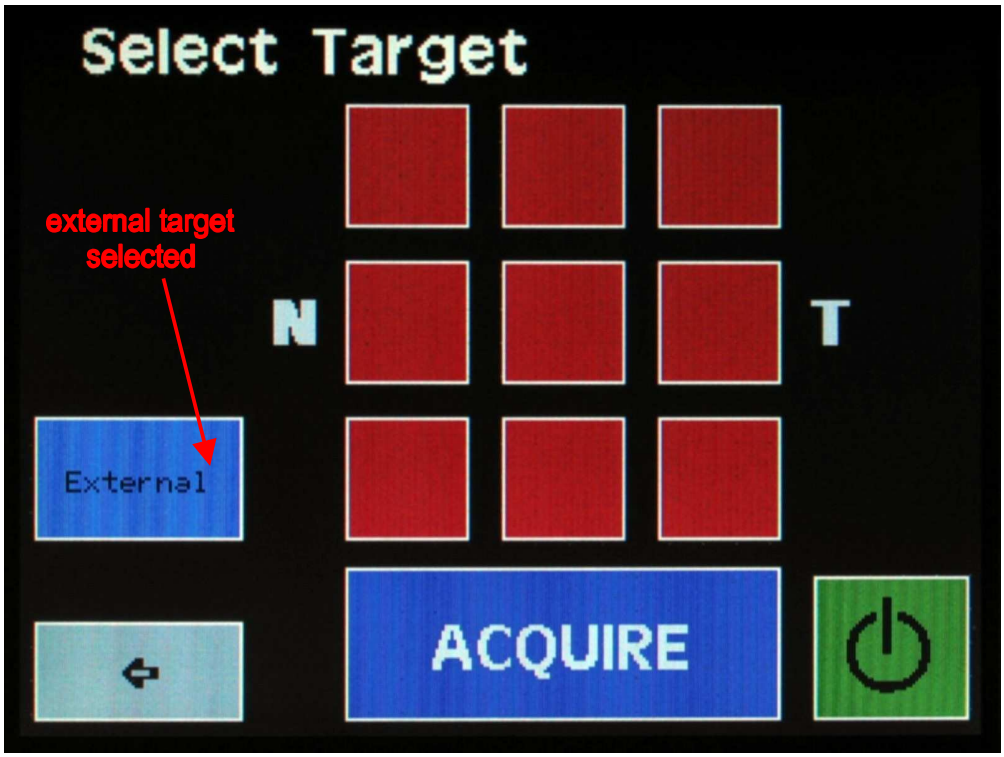
4.2.1.5 Main Screen

FA laser warmed up. Filter in Red Free / IR (reflectance) mode.



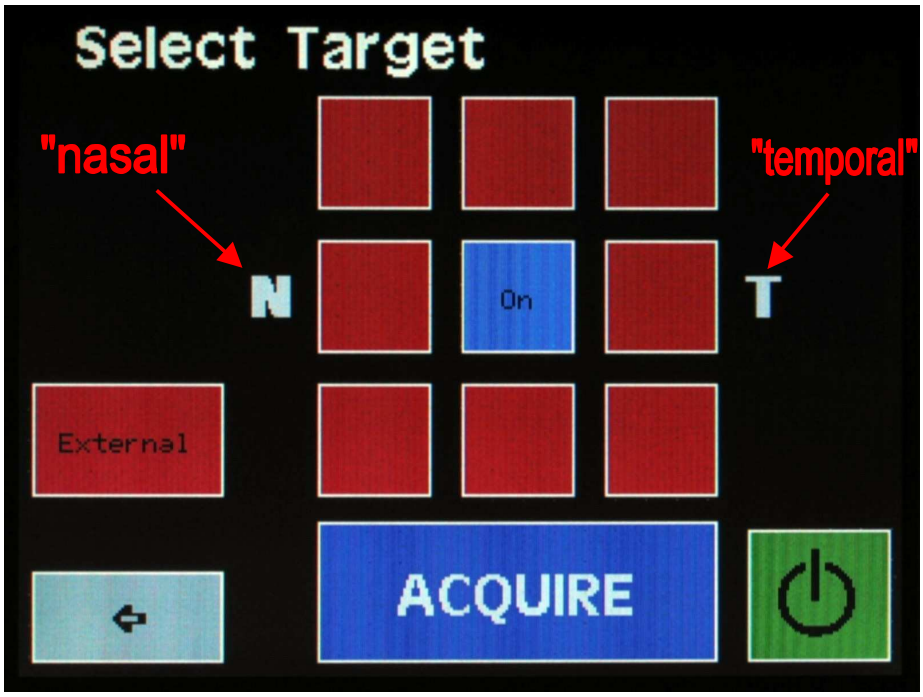
4.2.1.6 Target Select Screen

Press button (13) to select this screen. Choose either the external or one of the internal targets. To switch off all targets, press the button for the selected target again.



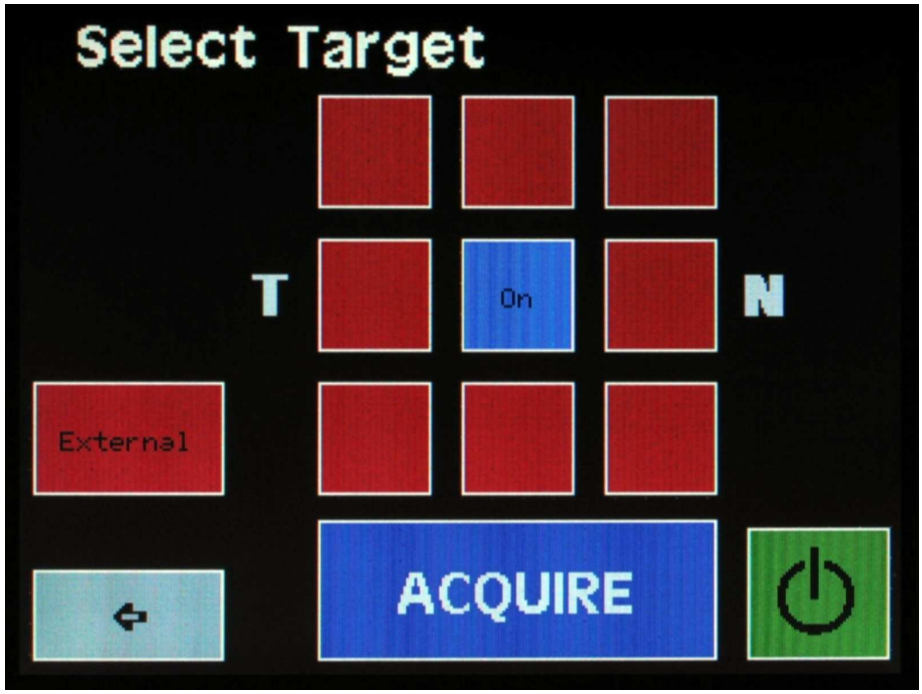
4.2.1.7 Target Select Screen

Central internal target selected. The letters right and left of the internal target buttons show where the temporal (**T**) and the nasal (**N**) side are.



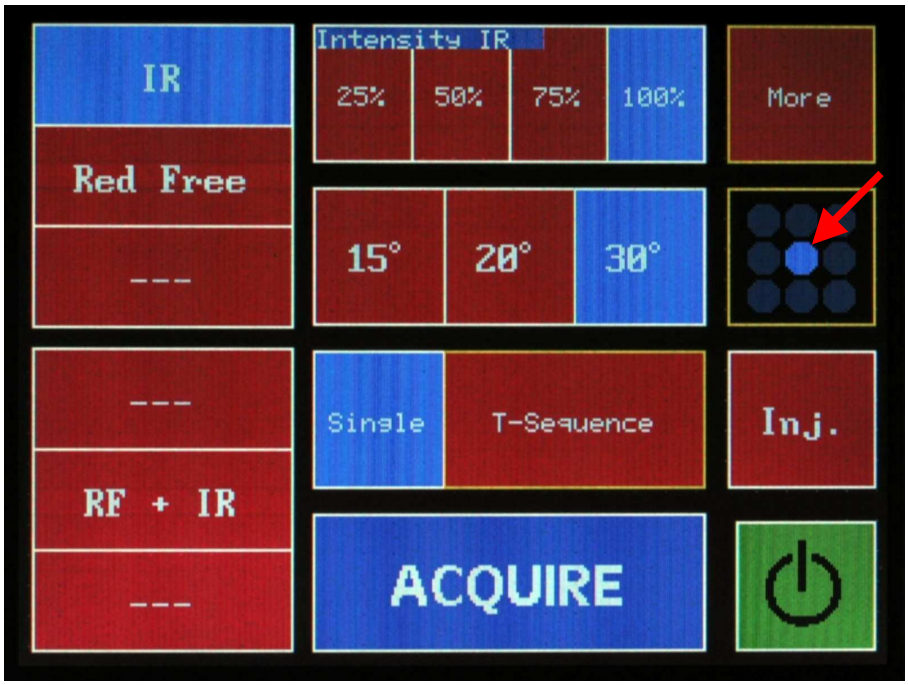
4.2.1.8 Target Select Screen

The T-N letters change whenever the camera head is moved to the other eye.



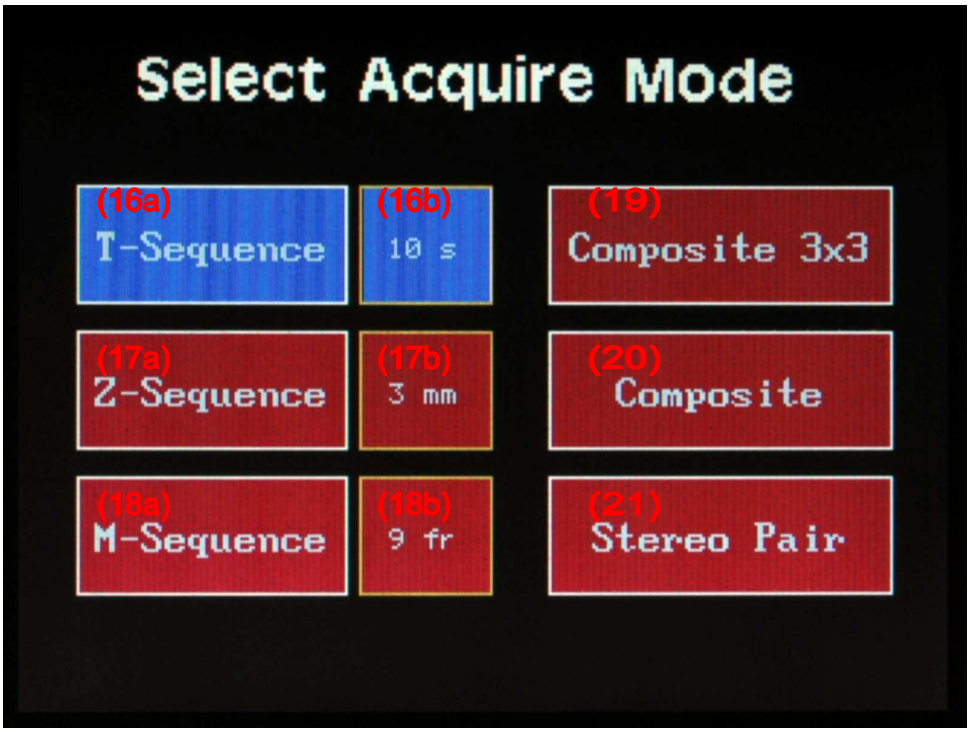
4.2.1.9 Main Screen

The selected target is indicated on the select target button.



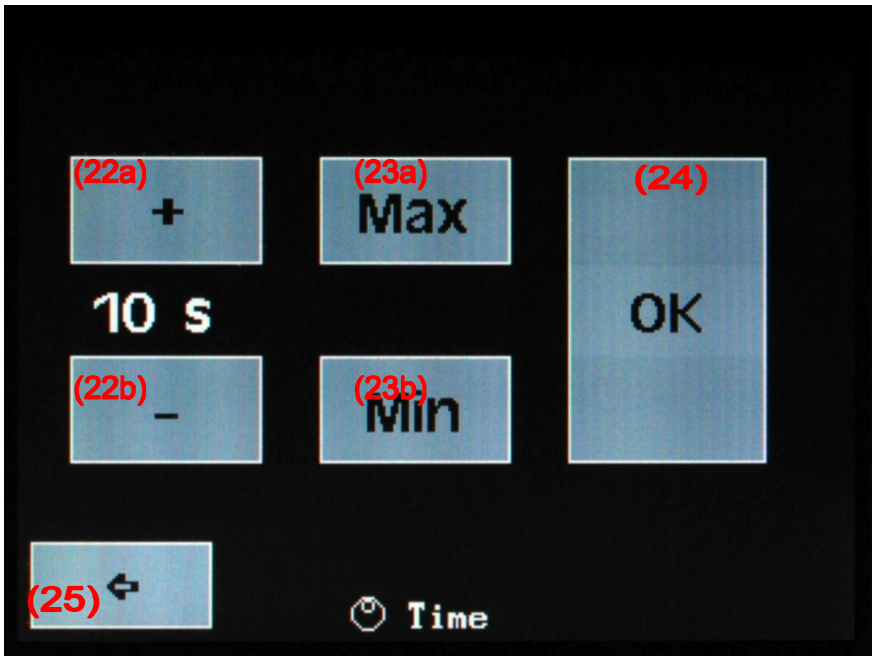
4.2.1.10 Acquire Mode Screen

Press button (10) on main screen once (twice if not active) to activate this screen. The buttons marked ‘b’ open a respective screen for selection of the respective parameter.



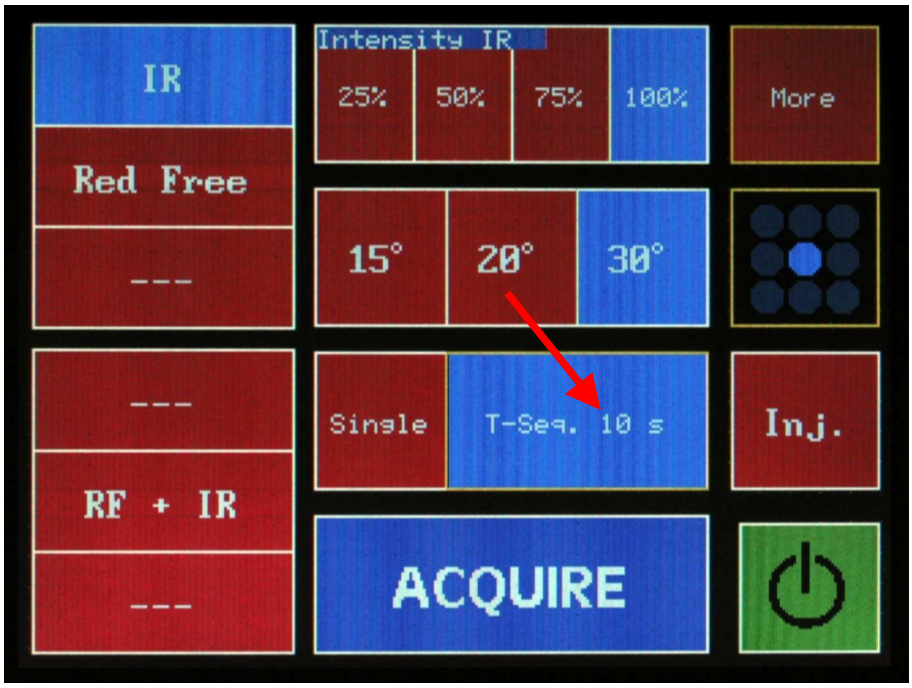
4.2.1.11 Select Time for T-Sequence Screen

Press button (16b) to get to this screen. Use +/- (button 23 a/b) to change the default time for a time series. Use Max/Min (button 23 a/b) to select maximum (until PC memory is full) or minimum time (1 s).



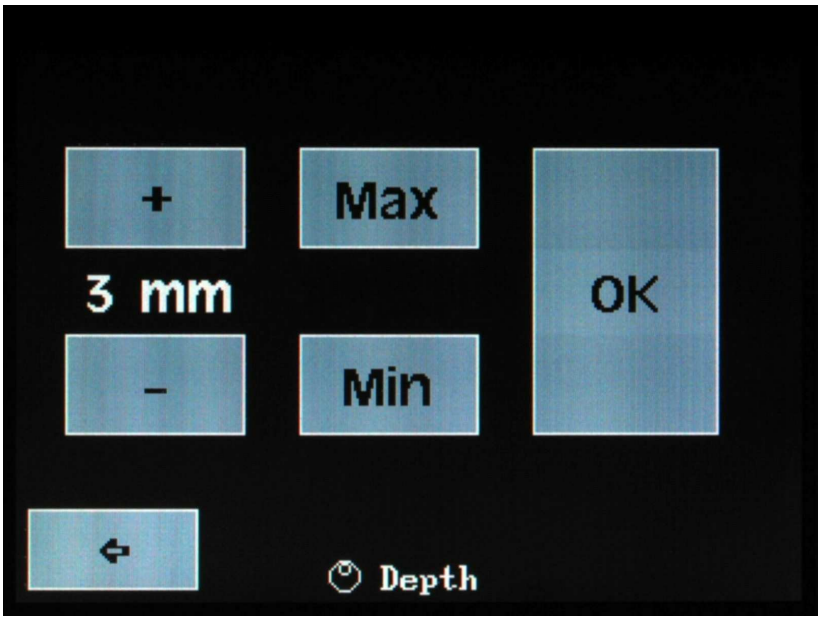
4.2.1.12 Main Screen

The length of the time series is indicated on button (10) now.



4.2.1.13 Select Depth for Z-Sequence Screen

On this screen the z-scan depth can be changed, similar to the time series before.

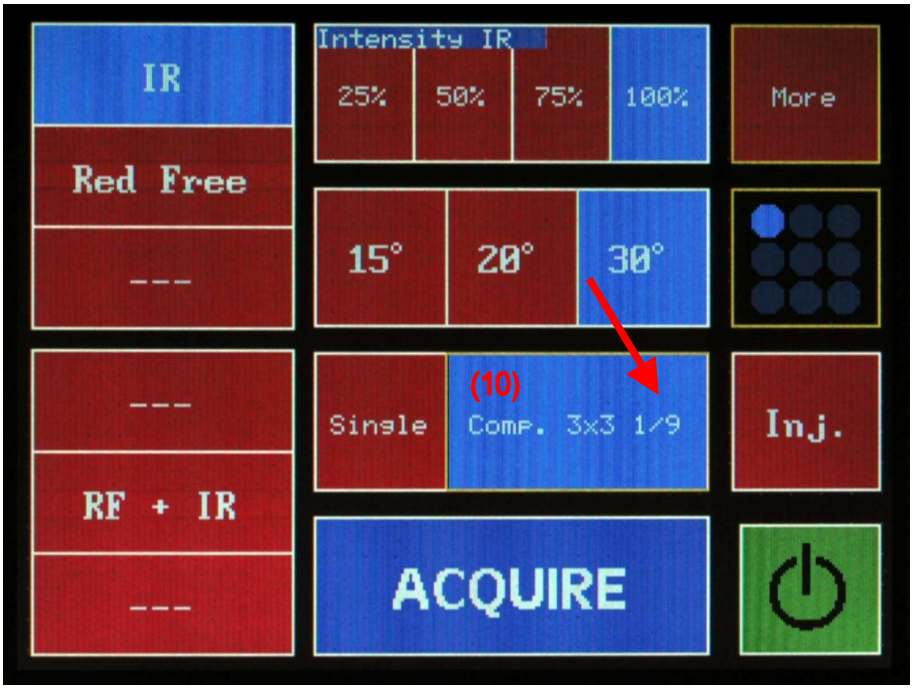


4.2.1.14 Select Frames for M-Sequence Screen

Change number of frames that are to be averaged to a mean image.

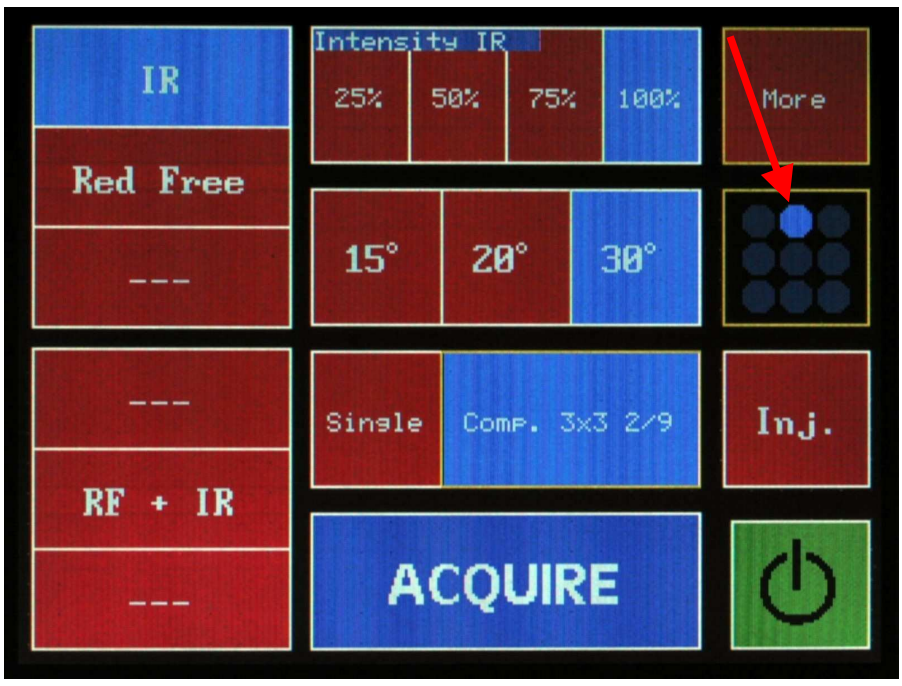
4.2.1.15 Main Screen: 3x3 Composite Mode

The current image number is indicated on button (10).



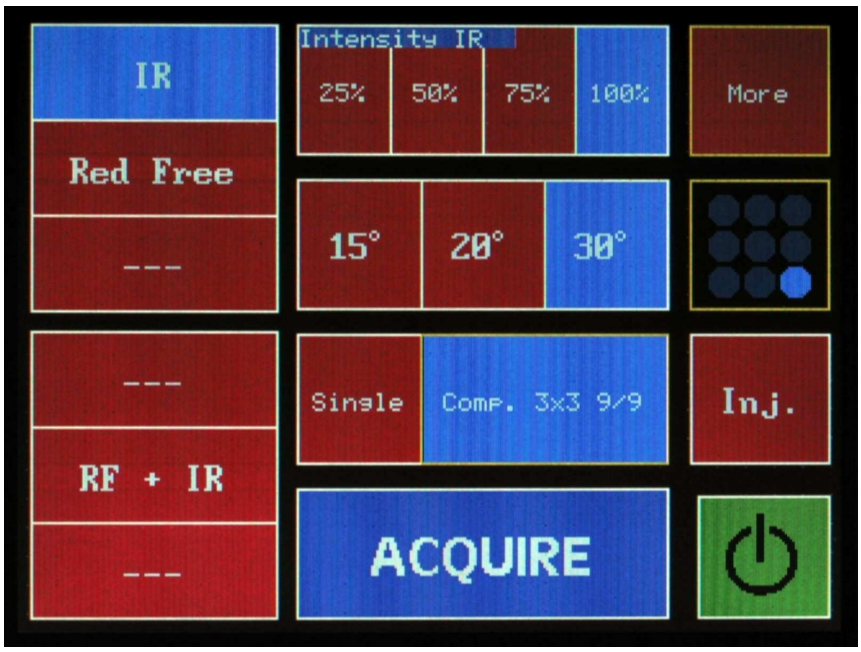
4.2.1.16 Main Screen: 3x3 Composite Mode

After acquisition of one frame the target changes automatically.



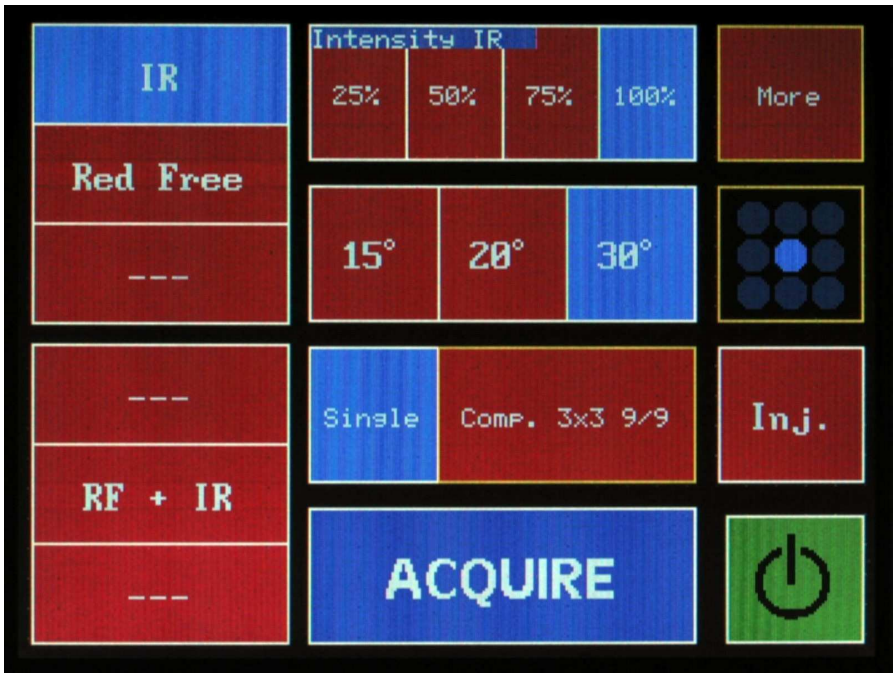
4.2.1.17 Main Screen: 3x3 Composite Mode

Acquisition of last image of the 3x3 composite.



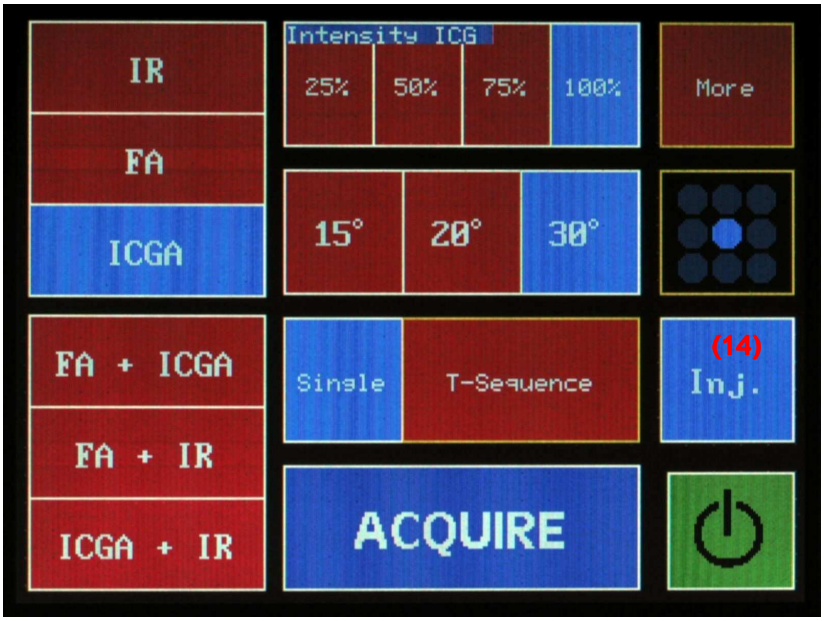
4.2.1.18 Main Screen

After the last 3x3 composite image, the mode changes back to “single” automatically.



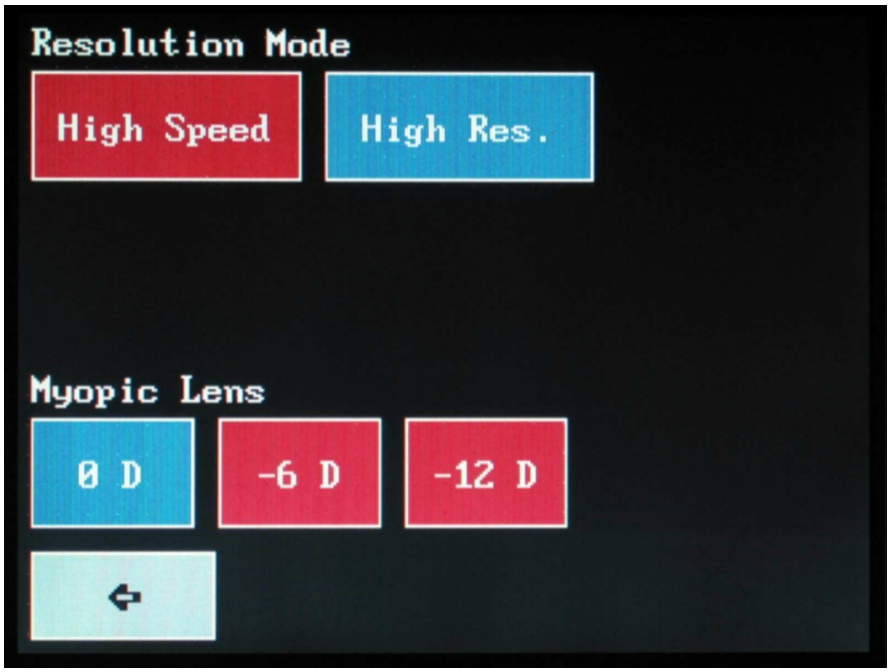
4.2.1.19 Main Screen: Injection Button Pressed

If an angiography mode is selected and no injection timer was started, button (14) will blink. Press this button to start the injection timer for the current mode. Afterwards, button (14) stops blinking and stays activated (blue).



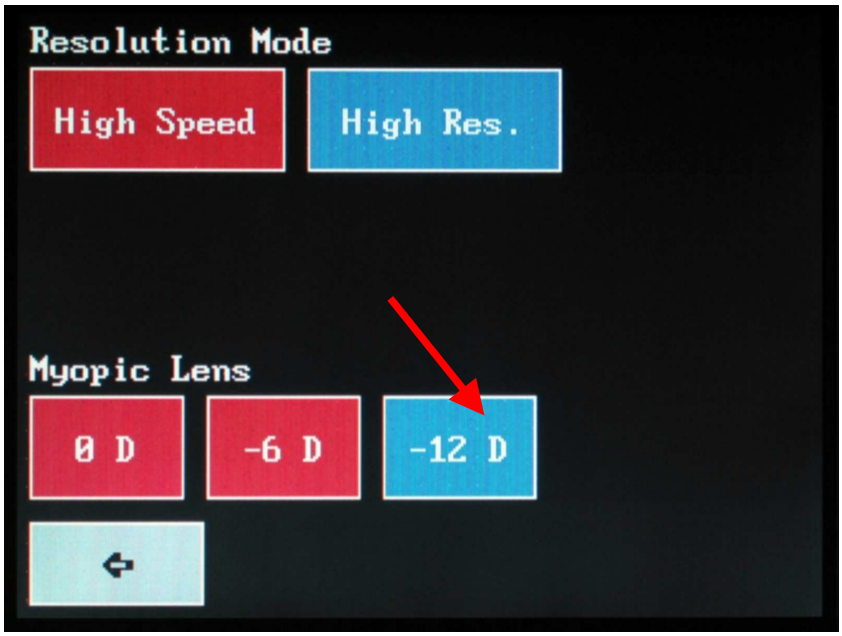
4.2.1.20 More Screen

This screen is reached via button (12) on the main screen. Select high speed or high-resolution mode here.



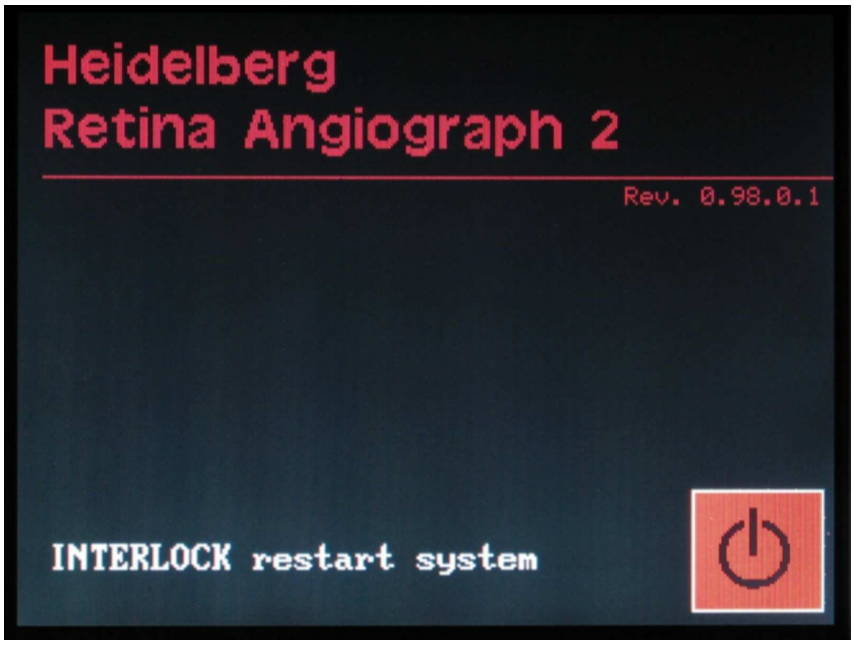
4.2.1.21 More Screen

A internal myopic lens can be activated here.



4.2.1.22 Freeze Screen: Interlock

An interlock can be triggered if the FA/red free laser power gets to high or if one or both scanners do not work properly.



4.2.2 Foot switch

The foot switch is used to acquire images. Its function is identical to pressing the ‘Acquire’ button of the touch panel.

4.2.3 Keyboard

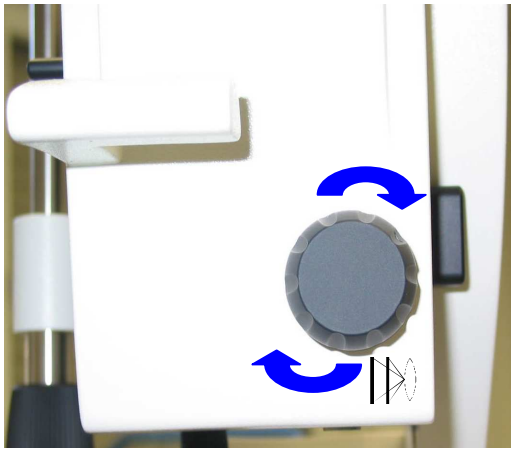
To use the Heidelberg Retina Angiograph 2 operation software, you need the computer keyboard in order to enter text and to control certain software functions. In the second case, function keys and special keys are often used. In this operation manual, the function keys are identified as 'F1', 'F2', etc.

4.2.4 Mouse

The Heidelberg Retina Angiograph 2 operation software is controlled via a graphical user interface (menu). For interaction, use your computer's mouse. To select a specific menu field, use the mouse to move the pointer to the field and press the left mouse button.

4.2.5 Focus knob

The knob at the backside of the camera head changes the focus. By turning this knob refractive errors of the patients eye can be compensated for. The current focus compensation is always shown at the lower left side of the PC acquisition module screen; units are diopters.

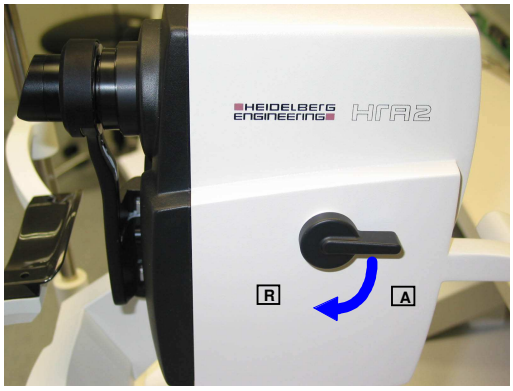


When examining a patient, set the focus compensation roughly to the patient’s spherical equivalent refraction and then turn the focus knob until you get a sharp image.

Keep in mind that the refraction for blue and infrared light differs slightly. Therefore, it is recommended to readjust the focus compensation when changing from red free or FA to infrared or ICGA mode or vice versa.

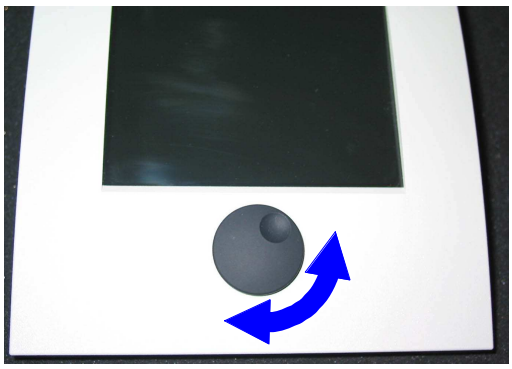
4.2.6 Filter Lever

By changing the position of this lever at the left side of the camera head the fluorescence filter is activated or deactivated. In the position marked by **A** the fluorescence angiography modes (FA, ICGA) are available, in the position marked by **R** only reflectance modes (IR, RF) are available.



4.2.7 Sensitivity Knob

Turning this knob increases (clockwise) or decreases (counterclockwise) the light sensitivity of the camera. Thus by turning the knob the image brightness changes (high sensitivity = high brightness, low sensitivity = low brightness).



The current sensitivity value is displayed on the lower left side of the PC acquisition module screen. Note that the image begins to blur when the sensitivity is set to values lower than 40 – 50.

5 Image Acquisition

5.1 Preparation

5.1.1 Preparing the Patient

No special preparation of the patient is required for an examination with the Heidelberg Retina Angiograph 2. The image acquisition is possible even without pupil dilation. As a general rule, however, dilation is recommended to significantly increase the signal-to-noise ratio and therefore the image quality. Refraction faults are corrected during the image acquisition by moving the focal plane of the system (see below). In case of an astigmatism of more than 2 diopters, glasses or contact lenses are recommended during the examination.

Prepare the injection of the fluorescent dye. In case of a simultaneous fluorescein and indocyanine angiography, inject both dyes at the same time.

5.1.2 Preparing the Instrument

The startup procedure is described in Chapter 4 “General Operating Information”.

5.2 Image Acquisition

The following is a description of the individual steps required for acquisition with the Heidelberg Retina Angiograph 2. It is subdivided into the settings required for the computer, the adjustment of the camera to the eye to be examined, and acquisition of the images.

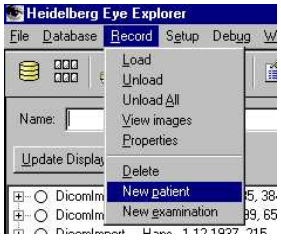
5.2.1 Creating a new patient record

First, create a new patient record in the Heidelberg Eye Explorer database. As in other Windows based programs, there a several ways to do that:

1. Using the tool bar

Click with the mouse on the New Patient symbol.

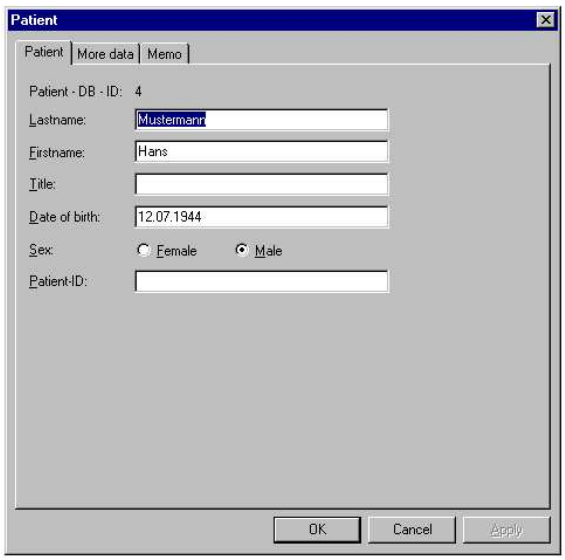
2. Using the menu



Open the menu "Record" and choose item New patient.

A dialog box will appear. Now you can enter the data for the new patient. After that, click on

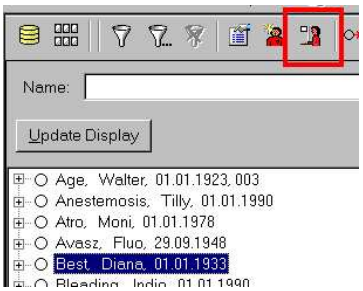
"OK" to create the new database record.



For the first time, the fields "Last name", "First name" and "Date of birth" are sufficient. All other fields may be empty.

After you have created a new patient record, the Heidelberg Eye Explorer will create a new examination, too. This will be explained further in the next step.

If you want to create a new examination for a patient that is already in the database, it is not necessary to re-enter all patient related data. Just select the desired patient and click on the "New Examination" tool bar button,



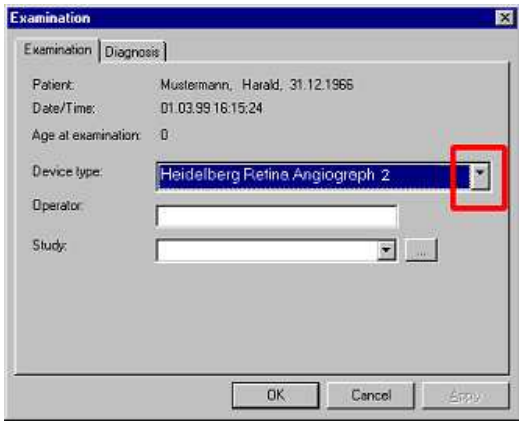
or press the right mouse button and select "New Examination" from the context pop up menu.

5.2.2 Creating a new examination

The creation of a new examination is the first step after you have entered a new patient. The Heidelberg Eye Explorer is using so called "acquisition modules" to create new examinations with the different types of ophthalmological acquisition devices. These modules are called "plug-ins", and can be easily integrated in an existing installation without changing the Heidelberg Eye Ex-

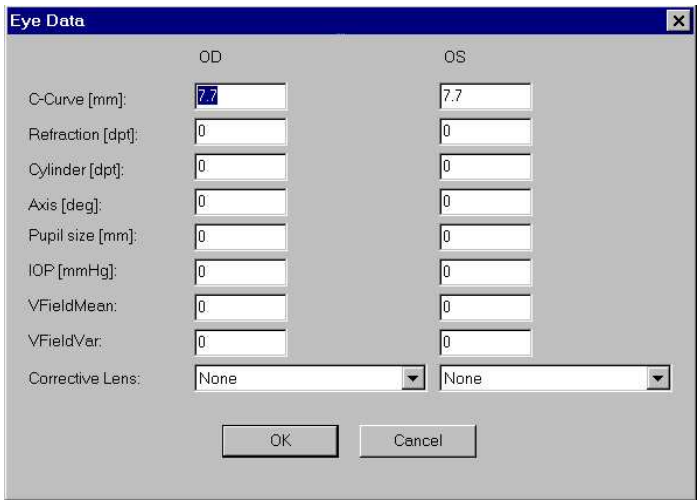
plorer itself. Thus, it is easy to adapt the Heidelberg Eye Explorer to any new image acquisition device.

The creation of a new examination starts with the following dialog box:



Choose "Heidelberg Retina Angiograph 2 (HRA 2)" as acquisition device.

After that, the following dialog will appear:



If you want, you can enter the eye parameters for both eyes. Only the cornea curvature will be of importance, because it will affect the measurement of distances and areas.

5.2.3 Touch Panel Settings and Patient Alignment

(1) The touch panel can now be used to control the image acquisition (see Chapter 4.2.1 “Touch Panel”). Usually, the following baseline settings for the touch panel are used.

- Select the infrared reflection acquisition mode (press the 'IR' button)
- Set scan angle to 30 degrees (using the 'scan size' button)

(2) Ask the patient to position their head and chin firmly against the headrest and chin rest. The height of the chin rest should be adjusted so that the eye being examined is located at the height of the red mark on the headrest. Ask the patient to look straight ahead or to stare at the fixation target with the eye that is not being examined.

(3) Adjust the focal plane to the refraction (spherical equivalent) of the examined eye (using the 'focus' button on the back of the camera).

(3) On the touch panel, press the 'freeze' button. The selected laser (infrared in the above baseline setting) will be switched on and the camera will start the image acquisition. If the camera is operating in simultaneous mode (see touch panel setting), two live images are visible on the screen. The image types are indicated below the images.

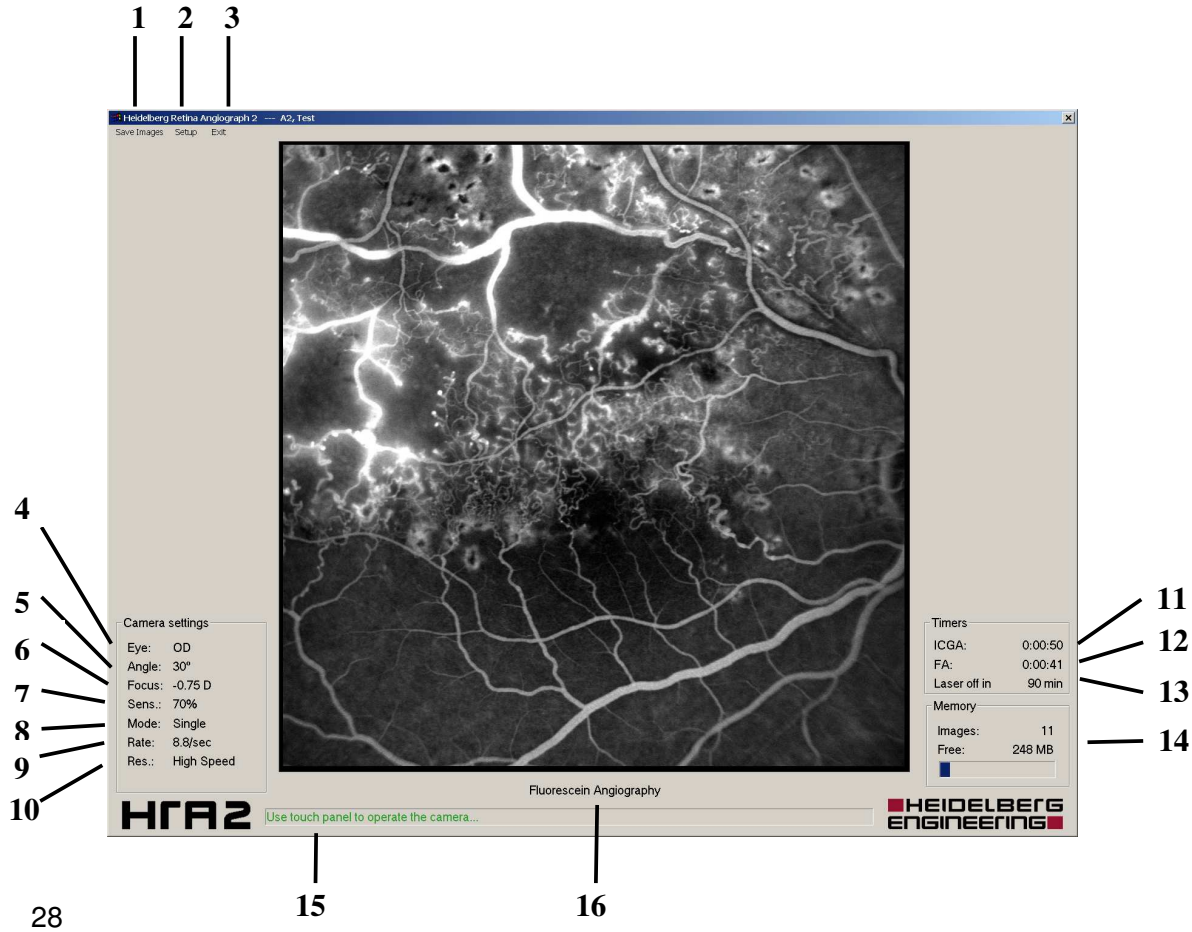
(4) Move the camera (up, down, right or left) to the center of the pupil and adjust the distance between the front edge of the objective tube and the examined eye to approximately 15 mm. As soon as the laser beam enters the pupil, you will see an image of the fundus of the eye on the screen. Now turn the camera on its horizontal and vertical axes so that the structure to be examined is visible on the screen. Move the camera slightly up/down and sideways until the image appears brightest.

(5) Then move the focal plane until the image is brightest and set the detector sensitivity (by turning the sensitivity button on the touch panel) so that you see a bright, but not overexposed picture. Overexposure causes white areas within the image.

(6) For the fine adjustment of the image, move the camera so that the structure to be examined is located precisely in the center of the image. Once again, move the camera slightly up/down and sideways until the image appears brightest. This is the point at which the laser beam falls directly into the center of the pupil of the examined eye.

5.2.4 Displaying and Changing Acquisition Parameters

During the image acquisition, the following dialog is displayed on the screen:



Short explanation for the different functions:

1 Save Images:	To store the acquired images to the Heidelberg Eye Explorer
2 Setup:	To set up the default resolution and the cyclic buffer size.
3 Exit:	To close the acquisition and to return to the Heidelberg Eye Explorer.
4 Eye:	Displays the actual eye to be examined.
5 Angle:	Displays the actual scan angle.
6 Focus:	Displays the actual focus / refraction
7 Sens.:	Displays the actual detector sensitivity (max. 99 %)
8 Mode:	Displays the actual acquisition mode setting (e.g. “Single”)
9 Rate :	Displays the actual scan rate of the live image. The scan rate depends on the scan angle, simultaneous or non-simultaneous acquisition, “high speed” or “high resolution” mode.
10 Res.:	Displays the actual resolution mode. Is either “High Speed” or “High Res.”
11 ICGA:	Displays the time that has passed since start of injection timer
12 FA:	Displays the time that has passed since start of injection timer
	Displays the actual scan depth (only important when you start series acquisition. (Depth = 0 is movie acquisition, else 3D-scan
13 Laser off in:	Remaining image acquisition time (seconds) until a 'laser safety timeout' will occur. The remaining time depends on the current setting of the scan angle. The image acquisition time is longest when the maximum scan angle is used.
14 Images:	Number of images already acquired into memory
x MB free:	Memory available for new images (in MB)
	The bar graphically represents the memory used by the already acquired images and the remaining free acquisition memory.
15 Status line:	Displays important messages to the user. Normal messages are shown in green, warnings are shown in yellow and errors or other very important messages are shown in red color.
16 Laser Mode:	Displays the actual laser mode of the live image displayed above.

5.2.5 Acquiring Images

(1) It is recommended that some reflectance images be acquired using the infrared or blue reflectance images before injection of the fluorescence dye. It is also recommended that some images be acquired with the FA mode before injection (auto-fluorescence image). Select the corresponding acquisition mode with the touch panel (i.e. ‘IR' for infrared reflectance images, 'RF' for blue reflectance images, 'FA' for auto-flourescence images). Press the 'Acquire' button or use the foot switch to acquire individual images.

(2) Set the laser mode control to the desired position: 'FA' for pure fluorescein angiography,

'ICGA' for pure indocyanine green angiography, or 'FA&ICGA' for simultaneous fluorescein/indocyanine green angiography.

(3) Set the parameters for image acquisition as follows:

- sensitivity of the detector to 80%
- For pure indocyanine green angiography:
- ICGA laser intensity to 100 %
- For simultaneous fluorescein/indocyanine green angiography:
- ICGA laser intensity to 50% - 75 %

Note: During simultaneous fluorescein/indocyanine green angiography, the intensity of the indocyanine green fluorescence is usually much brighter for the first 1 to 2 minutes than the fluorescein. To get the same brightness for both dyes we, therefore, recommend reducing the intensity of the infrared light for the early phase to 50% - 75%. After 1 or two minutes the laser intensity should be reset to maximum (100 %).

(4) Inject the fluorescent dye(s). Press the 'Inj' button on the touch panel during or immediately after injection to start the clocks(s) for the injection time. Please note that the clock(s) will always be started according to the selected acquisition mode.

(5) Select 'Single' or 'T-Sequence' on the touch panel if a automated image acquisition of a complete sequence is desired.

(6) Ask the patient not to move. Watch the image on the screen. As soon as you see the first fluorescence, press the 'Acquire' button on the control panel to start the image acquisition.

Note: The Heidelberg Retina Angiograph includes an internal cyclic buffer for live images acquired during the last 2 seconds (for setting the length of the cyclic buffer, see Chapter 4.3.1). These images are stored as soon as you hit the 'Acquire' button to initiate the acquisition of a time resolved image series. This ensures that the images of the last 2 seconds are stored before starting the time series.

(7) The image intensity will vary quickly during the inlet phase of the dye. Watch the image on the screen. Make sure the camera remains adjusted to the eye and the image brightness does not approach saturation. Overexposure causes white areas in the image. If necessary, readjust the image brightness using the 'sensitivity' control on the touch panel.

(8) Watch the number of acquired images in the bottom screen section. An acquisition of a T-Sequence can be stopped using the 'Stop' button on the touch panel.

(9) Immediately after interrupting the series acquisition, you are able to acquire single images using the 'Acquire' button again.

(10) Now, acquire individual images by pressing the 'Acquire' button on the control panel or the foot switch. Press the 'More' button on the touch panel to change between 'High resolution' and 'High speed' acquisition if required.

(11) Press the 'freeze' button and select the 'Save Images' menu item to store the acquired images to hard disk. After the storage procedure, the main memory of the PC is available for acquisition and you are able to acquire more images.

(12) To acquire a layered three-dimensional image, press on the 'T-Sequence' button twice and select 'Z-Sequence' and adjust the scan depth to an appropriate value. The right setting depends on the observed structure. A typical setting is 5 to 6 mm. Now press the 'Acquire' but-

ton. The system will automatically acquire and store images from 32 equidistant focal planes. After the acquisition of the focal series, the camera switches back to ‘Single’ mode.

(13) After completing the examination, leave the acquisition module by selecting 'Exit' from the menu bar. If you have not yet stored all images to hard disk, you will be prompted either to store or to delete these images.

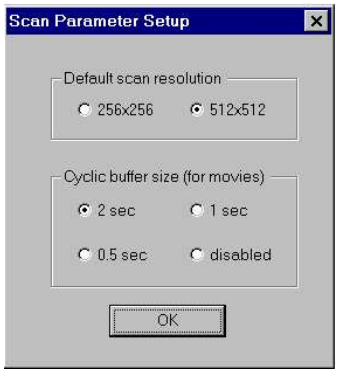
Note: It is often required to acquire late phase images 30 or more minutes after injecting the fluorescent dye. During this time, it is possible to examine the early phase of the next patient. For this purpose, exit the acquisition module (select 'Exit') and proceed as described above to create another patient record using the Heidelberg Eye Explorer. After acquiring the images of the second patient, load the examination of the first patient, switch to the acquisition menu, and continue with the image acquisition. The clocks for the injection dyes will be automatically set to the right patient and the new images will be appended to the existing images.

5.3 Image Acquisition Setup

The following setup functions are available inside the acquisition module.

5.3.1 Scan Parameter Setup

Select 'Setup' and 'Scan Parameter' to modify one of the following settings:



Default scan resolution:

High Resolution:	Open the acquisition module with max. 1536 x 1536 pixels(at 30°).
High Speed:	Open the acquisition module with max. 768 x 768 pixels (at 30°).

Cyclic buffer size (for movies):

After the 'series' button on the control panel has been pressed, the system will take the last 2 sec, 1 sec, 0.5 sec or 0 sec additionally.

5.3.2 Resetting the injection timers

If you want to reset the acquisition timers, e.g. because of a problem while injection, select 'Setup' and 'Reset Injection Timer(s)'. After that, you can restart the injection timers using the mouse or the 'I' key on the keyboard.

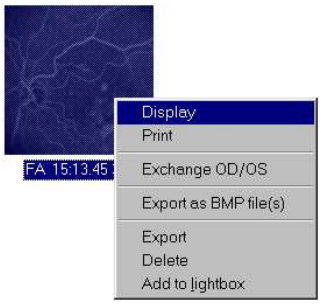
6 Image Inspection and Analysis

6.1 Image Viewing

6.1.1 Image Display

To view some of your images in the Heidelberg Eye Explorer Database, change to the Image View, where you will see all the small “thumbnail” images for every examination.

Double-click on an image icon to open the image in a separate window in its full resolution. You can also open the context pop up menu using the right mouse button and select the command "Display":



The following dialog will open in a separate window and will have its own menu and tool bar:

The first four buttons in this tool bar buttons are tools to create overlays on an image. A tool can be activated by a click on one of the buttons and will be visualized by a slightly modified mouse cursor. The different tools have the following meaning:

Image Overlays:

"Text"-Tool allows the creation of small text labels on top of the image. Just click with the mouse at the desired screen position and enter the text in the dialog box.

"Arrow"-tool allows the user to draw arrows in different colors, sizes and directions. Click with the mouse at the desired screen position and draw the arrow while you keep the button pressed.

"Region"-tool allows you to draw a closed outline of an arbitrary shaped region within the image. Draw the region with the left mouse button and use the right mouse button to automatically close the region.

"Distance"-tool allows the user to measure a distance in millimeters on the image. This will not work with all types of image data (dependent on the acquisition device). Click on the first location in the image with the right mouse button. Then release the button and move the mouse to the second measurement location.

Note: Overlays are stored in addition to the image contents. All overlays can be removed at any later time. To do that, open the menu "Overlay" and select "Remove all Overlays"!

Zooming:

1:1 Scales the image into the original resolution & size.

Scales the image to fit into the actual windows size. The window size can be adjusted with the mouse as usual.

You can use the "Zoom"-menu to select one of the predefined zoom factors, or just drag a frame about the area you want to zoom in.

Misc:

Show the previous / next image within the same examination.

Puts the image to the active lightbox.

Deletes the actual image and proceeds automatically to the next image within the same examination.

Warning! The image will be permanently removed and cannot be recovered!

If necessary, you can open another viewing window, if you want to compare two images on the screen. The "Windows" menu allows to automatically re-arrange or close all open viewing windows (try "Cascade" or "Tile").

The most important image processing options can be found in the "Image" menu. This menu will be discussed in the next section.

6.1.2 Image Enhancement

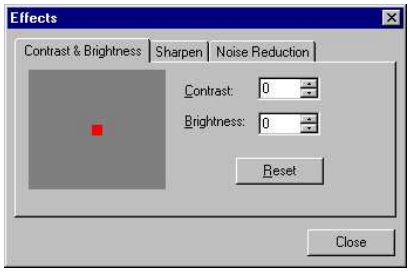
Note: None of the image enhancement tools within the Heidelberg Eye Explorer will change or modify the original image data. All changes will be stored separately, so they can be undone at any later time. Every time you access an image, the Heidelberg Eye Explorer will process the appropriate operations on the original image data.

Within the "Image" menu you can find the following enhancement functions:

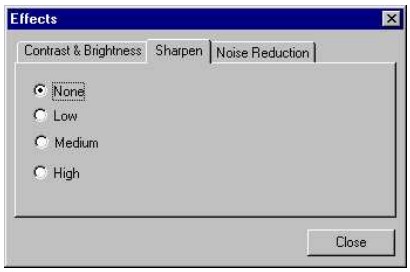
"Contrast & Brightness"

- "Sharpen" to enhance small image details
- "Noise Reduction" to enhance noisy images

Each function will open the following small dialog box. It has three tabs, one for each of the functions mentioned above. Within each tab you can set the parameters for the operation.



Contrast and brightness can be adjusted simultaneously using the red square. Just use the mouse to move the red square within the gray rectangle. You will quickly get a feeling on how the movement of the red square will affect the image. Alternatively you can enter two values (percentage) for contrast and brightness.

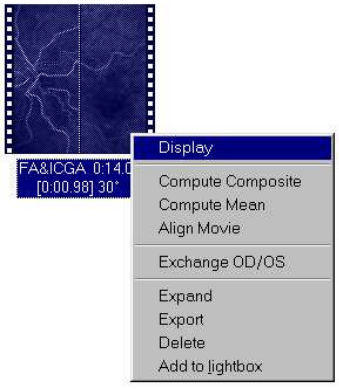


There are 4 different settings for "Sharpen" and "Noise Reduction", starting with "None" (default) to "High".

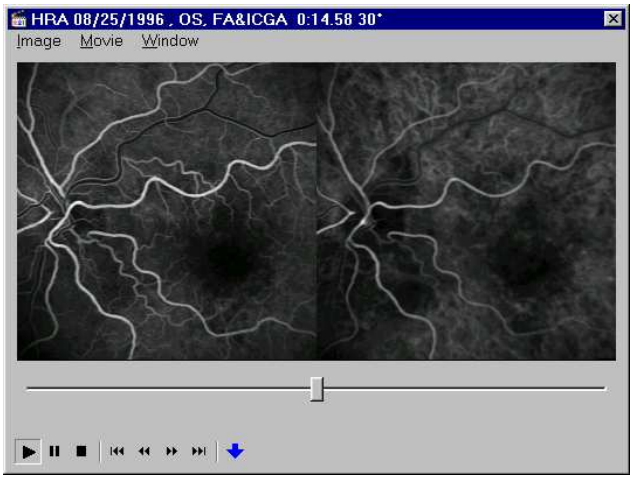
Click on the "Close" button to close the image enhancement dialog.

6.1.3 Movie Display

Double-click on a movie icon to play back the movie in a separate window in its full resolution. You can also open the context pop up menu using the right mouse button and select the command "Display":



The following dialog will opening in a separate window with its own menu and tool bar:



The toolbar at the bottom of the dialog is self-explanatory (i.e. Play, Pause, Stop, Jump to Start, Previous Image, Next Image, Jump to End)

Puts the actual image to the active lightbox.

Export as AVI:

Use menu "Movie" and select "Export as AVI..." to export the complete movie in the standard AVI file format.

Changing Play-Back image rate:

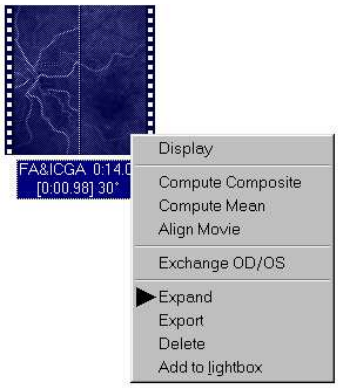
You can also change the play-back speed of the movie display using menu "Movie" and selection "xx frames per second". This enables you to play back the movie in higher speed or slow motion.

Play back with eye movement correction:

If the movie images have already been aligned (see section "Image processing" on how to do that), you can play back the movie without eye movements. Use "Movie" and select "Eye Movement Correction" to enable this feature.

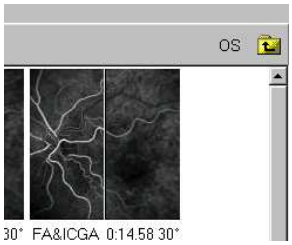
6.1.4 Expanding a Movie

If you would like to access all the images within a movie object, you can use the "Expand" command from the context menu to show up all single images:



Now you can work with the single images of the movie as with all other images on the top level (e.g. you can put images to the lightbox).

If you would like to close an expanded movie, use the small "directory up" button shown beside "OD" or "OS:

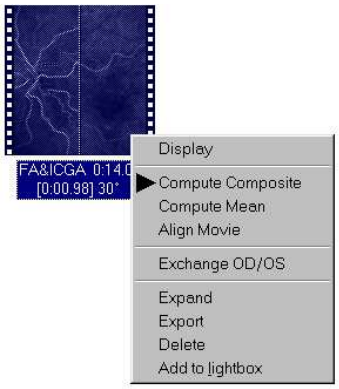


6.2 Image Processing

6.2.1 Computing Composite Images

The software is able to automatically combine an unlimited number of images to a single wide angle image composite. You can apply this operation directly on a movie symbol, or an arbitrary selection of single images.

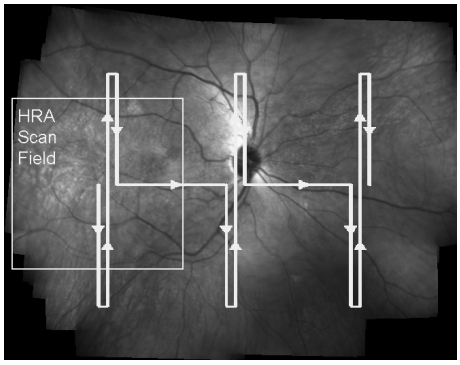
After you have selected the images, choose 'Compute Composite' from the right mouse button context menu to start the automatic computation of the composite image. Please be patient, depending on the number of selected images and on the performance of your computer system, the image processing may take up to several minutes,



When the calculation is ready, the software will display the resulting image and will appended this image at the end of the examination.

If you want to remove all source images after computation of the composite, it is necessary to compute the composite images ***before*** you archive the image data for this examination.

To acquire the images, it is recommended to set the image frame rate to 2 imgs/sec (using the '+' and '-' keys while the live image is on screen). To start the image acquisition, press the 'series' button on the control panel. While the camera is taking images (two per second), move the camera over the retina. The following moving pattern is recommended:



Start horizontally centered in the periphery. Swing the camera head downwards and upwards. Return back to the middle position. Go to the right. Again swing the camera downwards and upwards, etc.

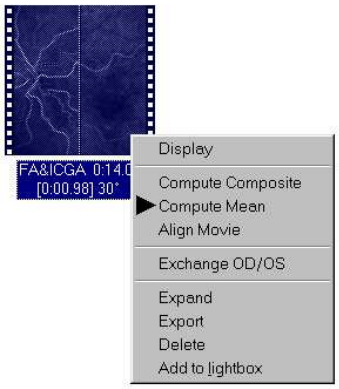
Proceed until you covered the whole area of interest. Stop the acquisition of images by pressing the 'freeze' button on the control panel. A reasonable value for the number of acquired images for the composite image is 30 up to 100.

You are not restricted to this moving pattern. After you've got some experience with this kind of acquisition, you will find the most suitable pattern for your needs.

Important: To obtain an image series suitable for the mosaic computation, it is important to avoid any movements of the camera mounting base or any adjustments of the height of the camera.

6.2.2 Computing Mean Images

To compute a mean image of several single images, select the images as described above and choose 'Compute Mean Image':

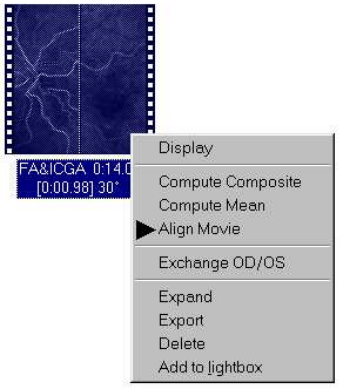


After the averaging procedure, the resulting image is appended at the end of the examination.

Averaging makes sense for images with a low signal to noise ratio, e.g. auto-flourescence images, late phase images or images of cataract patients. The signal to noise ratio increases by a factor of $\sqrt{n}$, where n is the number of images to be averaged (e.g. factor of 2 (for n=2) and factor of 4 (for n=16)). Because of this mathematical fact, using more then 16 images will only slightly enhance the resulting mean image quality.

6.2.3 Eye Movement Correction

To compute the eye movements within an angiographic sequence (movie), select the images as described in "Compute Composite Images" and select "Align Movie" or "Align Images" from the right mouse button menu:



After the alignment procedure, the computed eye movements will be stored to the movie, so it needs to be determined only once for every movie. When you playback the movie ("Display" or double-click), you can enable the "eye movement correction" from the "movie" menu.

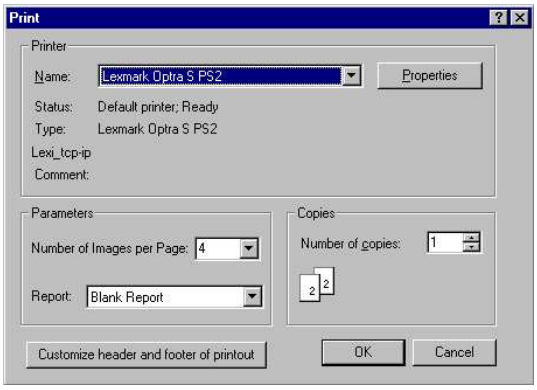
Note: The alignment of the images (translation and rotation) will cause a movement of the image borders.

6.3 Printing

To print images on an attached printer, select the desired images in the image view using the mouse. The selection of multiple images works as you are used to do it with the Windows® file explorer (Please refer to the Heidelberg Eye Explorer):

- A single click with the left mouse button selects one image.
- You can select multiple images if you keep the "Ctrl" key on the keyboard pressed while you select the images with the left mouse button.
- Draw a rectangular frame around the images to be selected.

Press the right mouse button to open the context pop up menu and select item "Print".



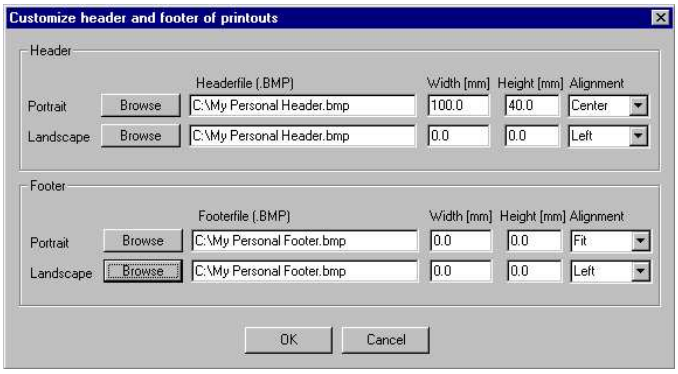
The upper part of the print dialog shows drop-down list with all installed printers. In the lower

part, you can define, how many images will be printed on each page (field "Number of Images per Page").

The Heidelberg Eye Explorer offers three types of print reports:

- Standard Report: Prints the header, footer and patient data.
- Anonymous Report: Prints the header, footer, but *no* patient data.
- Blank Report: Neither header and footer, nor patient data will be printed.

Click on the button "Customize header and footer of printout" to personalize the header and footer region.



You can define several file paths to your own bitmap files (BMP), which shell be printed in the header and footer region of the report. This can be used to put personal information like text and logos on the printout.

To create files in BMP format, you can use the program "Paint" which can be found in the Windows® 95/98/NT accessories.

7 Technical Data

7.1 Model Type and Manufacturer

Model Type: Heidelberg Retina Angiograph 2 (HRA2)

Manufacturer: Heidelberg Engineering GmbH
Gerhart-Hauptmann-Strasse 30
69221 Dossenheim / Germany

7.2 Environmental Specifications

Environmental Specification	Operating	Non Operating
Temperature	10°C to 40°C / 50°F to 104°F	-30°C to 60°C / -22F to 140F
Rel. Humidity	10% to 90%	10% to 100%

7.3 Power Supply and fuses

Specification	Tolerances
Input Voltage	100V to 240V.
Frequency	50Hz to 60Hz
Fuse 230V	1,25AT
Fuse 110V	2,5AT
HRA2 power consumption	70 W
PC components	See technical specifications for the PC- components

7.4 Isolation Transformer for PC- components

The isolation transformer has to be certified in accordance to the IEC 60601-1 and / or UL2601 standard.

Voltage / Manufacturer	Type / Capacity
230V / DEMETEC GmbH	IPs630K (630 VA)
110V / Tsi Power Corporation	ILC-1000 (1000W)

7.5 Laser Source

Laser	Specification
ICG excitation	Diod3e Laser 790nm, Laser Class 1
IR reflectance	Diode Laser 820nm Laser Class 1
FA excitation and blue reflectance	Solid state Laser 488nm Laser Class 1

7.6 Scanning Specifications

Function	Specification
Field of view:	30°x30°, 20°x20°, 15°x15°, wide field composite image to 120°
Focus Range	-12 to +12 diopters spherical, increments of 0,25dpt.
High Resolution Mode:	
Scan Size	30°x30°, 20°x20°, 15°x15°
Digitized Image Size (Pixels)	1536x1536, 1024x1024, 768x768
Max. Image Frequency	5 Hz, 7 Hz, 9 Hz
Scan Time/Image	96ms to192 ms
Digital Resolution	5µm/pixel
Z-Scan Depth	Max. 8mm
High Speed Mode	
Scan Size	30°x30°, 20°x20°, 15°x15°
Digitized Image Size (Pixels)	768x768, 512x512, 384x384
Max. Image Frequency (single)	9Hz, 12,5Hz, 16Hz
Max. Image Frequency (pairs)	5Hz, 7Hz, 9Hz
Scan Time/Image	48ms to 96ms
Digital Resolution	10µm/pixel
Z-Scan Depth	Max. 8mm

7.7 PC Requirements

Operating System	Windows 2000 professional or Windows XP professional
Processor	2 GHz Intel Pentium or AMD Processor
RAM	512 MB (or more)
VGA Board	High performance VGA board (with DVI interface for 1600x1200 resolution in case of a TFT monitor. E.g. ATI Radeon 8500)
Framegrabber	HE framegrabber (same as for HRT II system), requires 1 PCI slot
Ports	2 serial COM ports required (1 for normal operation, one for debugging)
Hard disk controller	IEE1394 (Firewire / I-link) interface controller
Internal hard disk	40 GB hard disk (for operating system and HRA 2 software only!)
Patient data storage	external firewire hard disk (> 200 GB)
Archive data storage	2nd external firewire hard disk (same size as data disk)

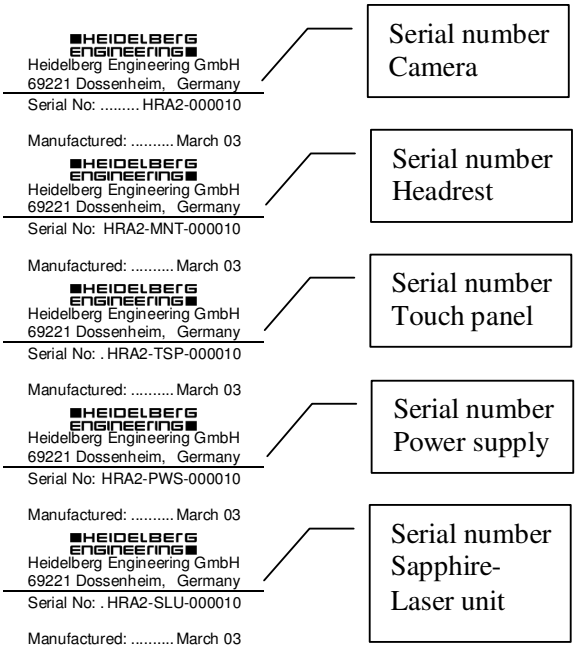
Monitor:

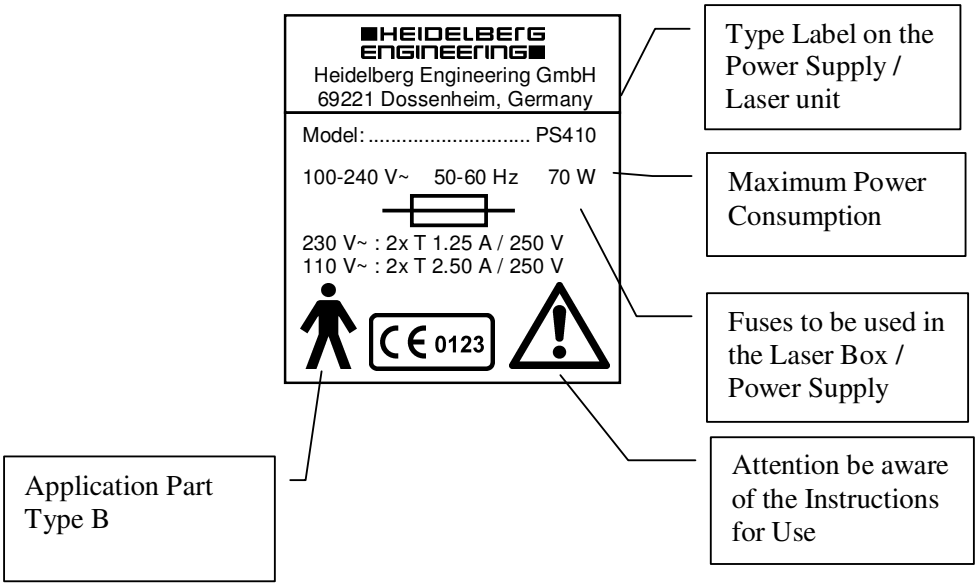
Technology	TFT (recommended), connected by DVI: • 19 " Iiyama AU 4831D • 20 " Viewsonic VP 201m CRT: • 21 " high quality monitor
Resolution	1600 x 1200 pixels **required** (the acquisition software will not start up with a smaller resolution!)

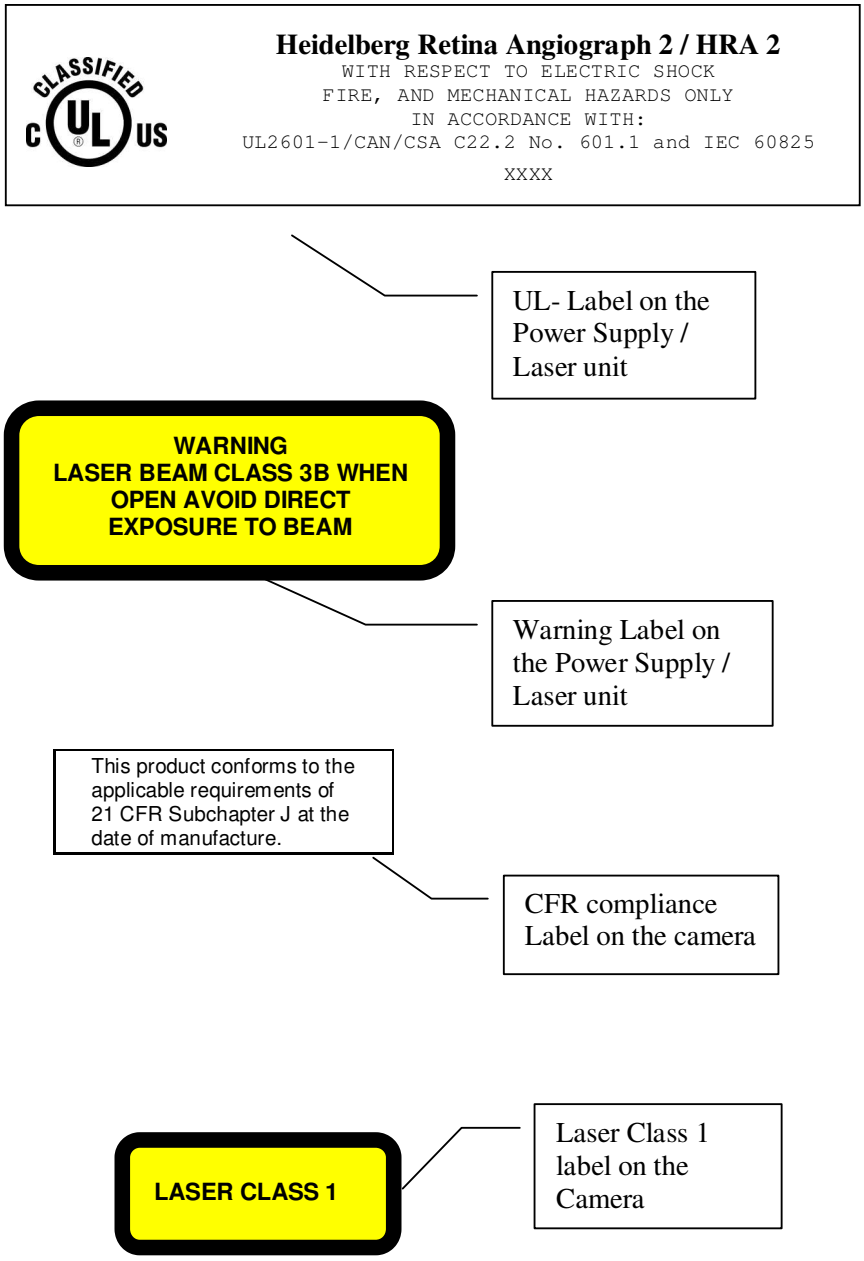
7.8 Service, Maintenance and Cleaning

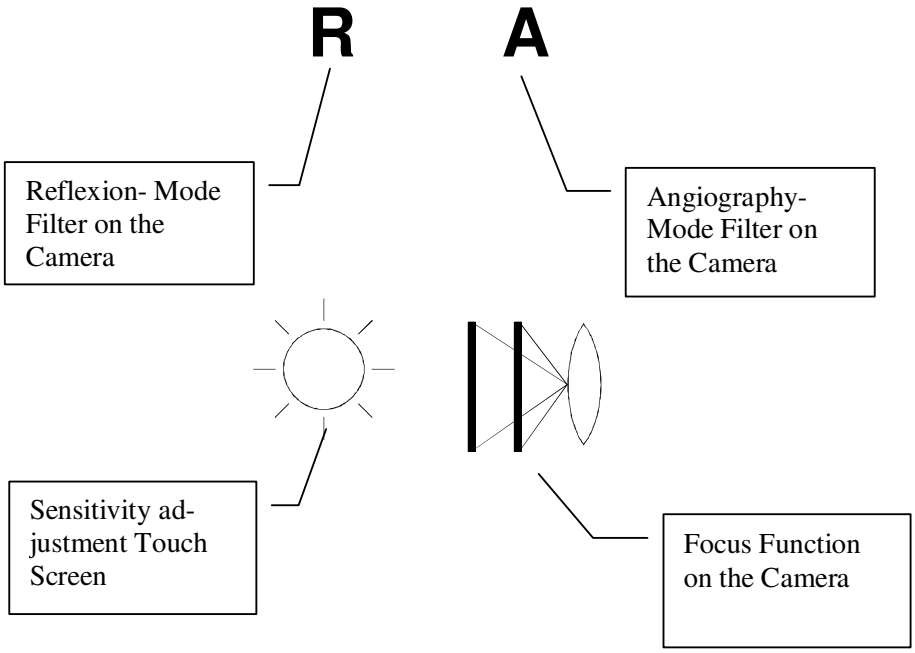
- Please be aware that authorized service personnel only can do Service and Repair operations of the HRA2. So do not open the device. You will lose the warranty. If the device fails please call your local distributor or the Heidelberg Engineering support department.
- The Heidelberg Retina Angiograph 2 is a precision optical measuring instrument. Protect the instrument against dust and moisture, and avoid shocks and the action of strong forces.
- The inclined glass plate on the front of the camera's objective lens should be carefully cleaned at regular intervals. For this purpose, it is best to use acetone and a soft cotton ball.
- The non-optical surfaces of the instrument can be cleaned and/or disinfected as usual whenever necessary. Before doing this, turn the instrument off and pull the power plug out.
- A yearly inspection of the device by a Heidelberg Engineering Service unit is highly recommended to grant proper and exact operating.

7.9 Labels


HEIDELBERG ENGINEERING
Heidelberg Engineering GmbH
69221 Dossenheim, Germany
Serial No: HRA2-000010
Manufactured: ..... March 03
Serial No: HRA2-MNT-000010
Serial No: . HRA2-TSP-000010
Serial No: HRA2-PWS-000010
Serial No: . HRA2-SLU-000010
Serial number Camera
Serial number Headrest
Serial number Touch panel
Serial number Power supply
Serial number Sapphire-Laser unit


HEIDELBERG ENGINEERING
Heidelberg Engineering GmbH
69221 Dossenheim, Germany
Model: PS410
100-240 V~ 50-60 Hz 70 W
230 V~ : 2x T 1.25 A / 250 V
110 V~ : 2x T 2.50 A / 250 V
CE 0123
Type Label on the Power Supply / Laser unit
Maximum Power Consumption
Fuses to be used in the Laser Box / Power Supply
Attention be aware of the Instructions for Use
Application Part Type B


Heidelberg Retina Angiograph 2 / HRA 2
WITH RESPECT TO ELECTRIC SHOCK
FIRE, AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH:
UL2601-1/CAN/CSA C22.2 No. 601.1 and IEC 60825
XXXX
UL- Label on the Power Supply / Laser unit
WARNING
LASER BEAM CLASS 3B WHEN OPEN AVOID DIRECT EXPOSURE TO BEAM
Warning Label on the Power Supply / Laser unit
This product conforms to the applicable requirements of 21 CFR Subchapter J at the date of manufacture.
CFR compliance Label on the camera
LASER CLASS 1
Laser Class 1 label on the Camera



7.10 Disposal

Only Heidelberg Engineering shall dispose the device.